

Dermira and UCB announce start of Phase 3 program for CIMZIA[®] (certolizumab pegol) in psoriasis

- Phase 3 program aims to address patient need for alternative treatment options in moderate-to-severe psoriasis
- Program includes the first Phase 3 study in psoriasis comparing two anti-TNFs
- Based on current enrollment projections, top-line data from these studies are expected in 2017

Menlo Park, Calif., and Brussels, Belgium – 8th January 2015, 0800 CET – Dermira, Inc., a specialty biopharmaceutical company focused on bringing innovative and differentiated medical dermatology products to dermatologists and their patients (NASDAQ: DERM), and UCB, a global biopharmaceutical leader (Euronext: UCB), announced today that the first patients have been dosed in the Phase 3 clinical program designed to evaluate the efficacy and safety of CIMZIA[®] (certolizumab pegol) in adult patients with moderate-to-severe chronic plaque psoriasis. This is an important step forward in the collaboration between Dermira and UCB in the development of solutions for patients with moderate-to-severe plaque psoriasis, a severe autoimmune disease.¹ CIMZIA[®] is not currently approved for the treatment of psoriasis by any regulatory authority worldwide.

“We are excited to have advanced CIMZIA[®] into Phase 3 trials in moderate-to-severe plaque psoriasis with the goal of extending product access to patients who live with this debilitating skin disease,” stated Tom Wiggans, Chief Executive Officer, Dermira. “CIMZIA[®] is approved as a treatment option for patients living with a range of inflammatory diseases, and we are proud to be working with UCB with the goal of bringing this important therapeutic option to the millions of patients with moderate-to-severe psoriasis.”

“CIMZIA[®] is UCB’s lead product, and our collaboration with Dermira and the Phase 3 psoriasis program demonstrate our continued commitment to further investigate CIMZIA[®] in an effort to potentially broaden patient access and improve outcomes for people living with this chronic autoimmune disorder.” said Professor Dr. Iris Loew-Friedrich, Chief Medical Officer and Executive Vice President, UCB.

The Phase 3 clinical development program, which is led by Dermira in collaboration with UCB, is designed to evaluate the efficacy and safety of certolizumab pegol in the treatment of adult patients with moderate-to-severe chronic plaque psoriasis. It consists of three studies that aim to enroll a total of approximately 1,000 patients, including patients with and without prior treatment experience with biologic products.

Two of the studies, CIMPASI-1 and CIMPASI-2, are randomized, blinded, parallel group, placebo-controlled, multi-center studies designed to evaluate the efficacy and safety of certolizumab pegol in

the treatment of patients with moderate-to-severe chronic plaque psoriasis. The third study, CIMPACT, is a randomized, blinded, parallel group, placebo-controlled and blinded, active-controlled, multi-center study with a primary objective of comparing the efficacy and safety of certolizumab pegol to placebo in the treatment of patients with moderate-to-severe chronic plaque psoriasis. A secondary objective of the study is to compare the efficacy and safety of certolizumab pegol to etanercept (marketed as ENBREL®).*

The primary endpoint in CIMPACT, the placebo- and active-controlled study, is the percentage of patients on certolizumab pegol achieving 75% or greater disease improvement from baseline, compared with placebo, as measured by the Psoriasis Area and Severity Index (PASI 75) at week 12. CIMPASI-1 and CIMPASI-2, the placebo-controlled studies, have co-primary endpoints comprising both PASI 75 and the percentage of patients achieving at least a two-point improvement to a final score representing clear or almost clear skin on a five-point Physician's Global Assessment scale, each compared with placebo, at week 16. Patients in each trial may receive blinded treatment for up to 48 weeks and, based on current enrollment projections, top-line data from these studies are expected in 2017. Patients in each study may receive open-label treatment with certolizumab pegol for up to an additional 96 weeks.

In a completed, 176-patient Phase 2 study, PASI 75 was achieved by 75% (44/59), 83% (48/58) and 7% (4/59) of patients in the certolizumab pegol 200 mg, 400 mg and placebo groups, respectively ($p < 0.001$ for both treatment arms vs. placebo). These Phase 2 results support the continued Phase 3 clinical program for the development of certolizumab pegol in psoriasis.²

Under the terms of the agreement announced in July 2014, Dermira obtained exclusive rights to develop certolizumab pegol in psoriasis in the United States, Canada and the European Union. Subject to regulatory approval of CIMZIA® in psoriasis, Dermira is granted an exclusive commercial license to market CIMZIA® to dermatologists in the US and Canada. The dosing of the first patient in the Phase 3 program has triggered a milestone payment of \$7.3 million payable by UCB to Dermira in the first quarter of 2015.

**ENBREL® (etanercept) is a registered trademark of Amgen Inc.*

About Psoriasis¹

Psoriasis is a common, chronic, relapsing, immune-mediated, inflammatory disorder with primary involvement of the skin. It affects two to three per-cent of the world's population – approximately 125 million people worldwide. Psoriasis signs and symptoms can vary from person to person but may include red patches of skin covered with silvery scales, dry, cracked skin that may bleed and thickened, pitted or ridged nails.

About CIMZIA®

CIMZIA® is the only Fc-free, PEGylated anti-TNF (Tumor Necrosis Factor). CIMZIA® has a high affinity for human TNF-alpha, selectively neutralizing the pathophysiological effects of TNF-alpha.

About CIMZIA® in the US³

In the US, CIMZIA® is approved for the treatment of adults with moderately to severely active rheumatoid arthritis, for the treatment of adults with active psoriatic arthritis (PsA) and for adults with active ankylosing spondylitis (AS). In addition, it is approved for reducing signs and symptoms of

Crohn's disease and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy.

Important Safety Information about CIMZIA[®] in the US

Risk of Serious Infections and Malignancy

Patients treated with CIMZIA[®] are at an increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. CIMZIA[®] should be discontinued if a patient develops a serious infection or sepsis. Reported infections include:

- **Active tuberculosis, including reactivation of latent tuberculosis. Patients with tuberculosis have frequently presented with disseminated or extrapulmonary disease. Patients should be tested for latent tuberculosis before CIMZIA[®] use and during therapy. Treatment for latent infection should be initiated prior to CIMZIA[®] use.**
- **Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Empiric anti-fungal therapy should be considered in patients at risk for invasive fungal infections who develop severe systemic illness.**
- **Bacterial, viral and other infections due to opportunistic pathogens, including Legionella and Listeria.**

The risks and benefits of treatment with CIMZIA[®] should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection. Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with CIMZIA[®], including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy.

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, of which CIMZIA[®] is a member. CIMZIA[®] is not indicated for use in pediatric patients.

Patients treated with CIMZIA[®] are at an increased risk for developing serious infections involving various organ systems and sites that may lead to hospitalization or death. Opportunistic infections due to bacterial, mycobacterial, invasive fungal, viral, parasitic, or other opportunistic pathogens including aspergillosis, blastomycosis, candidiasis, coccidioidomycosis, histoplasmosis, legionellosis, listeriosis, pneumocystosis and tuberculosis have been reported with TNF blockers. Patients have frequently presented with disseminated rather than localized disease.

Treatment with CIMZIA[®] should not be initiated in patients with an active infection, including clinically important localized infections. CIMZIA[®] should be discontinued if a patient develops a serious infection or sepsis. Patients greater than 65 years of age, patients with co-morbid conditions, and/or patients taking concomitant immunosuppressants (e.g., corticosteroids or methotrexate) may be at a greater risk of infection. Patients who develop a new infection during treatment with CIMZIA[®] should

be closely monitored, undergo a prompt and complete diagnostic workup appropriate for immunocompromised patients, and appropriate antimicrobial therapy should be initiated. Appropriate empiric antifungal therapy should also be considered while a diagnostic workup is performed for patients who develop a serious systemic illness and reside or travel in regions where mycoses are endemic.

Malignancies

During controlled and open-labeled portions of CIMZIA[®] studies of Crohn's disease and other diseases, malignancies (excluding non-melanoma skin cancer) were observed at a rate of 0.5 per 100 patient-years among 4,650 CIMZIA[®]-treated patients versus a rate of 0.6 per 100 patient-years among 1,319 placebo-treated patients. In studies of CIMZIA[®] for Crohn's disease and other investigational uses, there was one case of lymphoma among 2,657 CIMZIA[®]-treated patients and one case of Hodgkin lymphoma among 1,319 placebo-treated patients. In CIMZIA[®] RA clinical trials (placebo-controlled and open label), a total of three cases of lymphoma were observed among 2,367 patients. This is approximately 2-fold higher than expected in the general population. Patients with RA, particularly those with highly active disease, are at a higher risk for the development of lymphoma. The potential role of TNF blocker therapy in the development of malignancies is not known.

Malignancies, some fatal, have been reported among children, adolescents, and young adults who received treatment with TNF-blocking agents (initiation of therapy ≤ 18 years of age), of which CIMZIA[®] is a member. Approximately half of the cases were lymphoma (including Hodgkin's and non-Hodgkin's lymphoma), while the other cases represented a variety of different malignancies and included rare malignancies associated with immunosuppression and malignancies not usually observed in children and adolescents. Most of the patients were receiving concomitant immunosuppressants.

Cases of acute and chronic leukemia have been reported with TNF-blocker use. Even in the absence of TNF-blocker therapy, patients with RA may be at a higher risk (approximately 2-fold) than the general population for developing leukemia.

Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma that has a very aggressive disease course and is usually fatal, have been reported in patients treated with TNF blockers, including CIMZIA[®]. The majority of reported TNF blocker cases occurred in adolescent and young adult males with Crohn's disease or ulcerative colitis. Almost all of these patients had received treatment with the immunosuppressants azathioprine and/or 6-mercaptopurine (6-MP) concomitantly with a TNF blocker at or prior to diagnosis. Carefully assess the risks and benefits of treatment with CIMZIA[®], especially in these patient types.

Periodic skin examinations are recommended for all patients, particularly those with risk factors for skin cancer.

Heart Failure

Cases of worsening congestive heart failure (CHF) and new onset CHF have been reported with TNF blockers. CIMZIA[®] has not been formally studied in patients with CHF. Exercise caution when using CIMZIA[®] in patients who have heart failure and monitor them carefully.

Hypersensitivity

Symptoms compatible with hypersensitivity reactions, including angioedema, dyspnea, hypotension, rash, serum sickness, and urticaria, have been reported rarely following CIMZIA[®] administration. Some of these reactions occurred after the first administration of CIMZIA[®]. If such reactions occur, discontinue further administration of CIMZIA[®] and institute appropriate therapy.

Hepatitis B Reactivation

Use of TNF blockers, including CIMZIA[®], has been associated with reactivation of hepatitis B virus (HBV) in patients who are chronic carriers of this virus. Some cases have been fatal. Test patients for HBV infection before initiating treatment with CIMZIA[®]. Exercise caution in prescribing CIMZIA[®] for patients identified as carriers of HBV, with careful evaluation and monitoring prior to and during treatment. In patients who develop HBV reactivation, discontinue CIMZIA[®] and initiate effective anti-viral therapy with appropriate supportive treatment.

Neurologic Reactions

Use of TNF blockers, including CIMZIA[®], has been associated with rare cases of new onset or exacerbation of clinical symptoms and/or radiographic evidence of central nervous system demyelinating disease, including multiple sclerosis, and with peripheral demyelinating disease, including Guillain-Barré syndrome. Rare cases of neurological disorders, including seizure disorder, optic neuritis, and peripheral neuropathy have been reported in patients treated with CIMZIA[®]. Exercise caution in considering the use of CIMZIA[®] in patients with these disorders.

Hematologic Reactions

Rare reports of pancytopenia, including aplastic anemia, have been reported with TNF blockers. Medically significant cytopenia (e.g., leukopenia, pancytopenia, thrombocytopenia) has been infrequently reported with CIMZIA[®]. Advise all patients to seek immediate medical attention if they develop signs and symptoms suggestive of blood dyscrasias or infection (e.g., persistent fever, bruising, bleeding, pallor) while on CIMZIA[®]. Consider discontinuation of CIMZIA[®] therapy in patients with confirmed significant hematologic abnormalities.

Drug Interactions

An increased risk of serious infections has been seen in clinical trials of other TNF blocking agents used in combination with anakinra or abatacept. Formal drug interaction studies have not been performed with rituximab or natalizumab; however, because of the nature of the adverse events seen with these combinations with TNF blocker therapy, similar toxicities may also result from the use of CIMZIA[®] in these combinations. Therefore, the combination of CIMZIA[®] with anakinra, abatacept, rituximab, or natalizumab is not recommended. Interference with certain coagulation assays has been detected in patients treated with CIMZIA[®]. There is no evidence that CIMZIA[®] therapy has an effect on in vivo coagulation. CIMZIA[®] may cause erroneously elevated a PTT assay results in patients without coagulation abnormalities.

Autoimmunity

Treatment with CIMZIA[®] may result in the formation of autoantibodies and, rarely, in the development of a lupus-like syndrome. Discontinue treatment if symptoms of lupus-like syndrome develop.

Immunizations

Do not administer live vaccines or live-attenuated vaccines concurrently with CIMZIA[®].

Adverse Reactions

In controlled Crohn's clinical trials, the most common adverse events that occurred in $\geq 5\%$ of CIMZIA[®] patients (n=620) and more frequently than with placebo (n=614) were upper respiratory infection (20% CIMZIA[®], 13% placebo), urinary tract infection (7% CIMZIA[®], 6% placebo), and arthralgia (6% CIMZIA[®], 4% placebo). The proportion of patients who discontinued treatment due to adverse reactions in the controlled clinical studies was 8% for CIMZIA[®] and 7% for placebo.

In controlled RA clinical trials, the most common adverse events that occurred in $\geq 3\%$ of patients taking CIMZIA[®] 200 mg every other week with concomitant methotrexate (n=640) and more frequently than with placebo with concomitant methotrexate (n=324) were upper respiratory tract infection (6% CIMZIA[®], 2% placebo), headache (5% CIMZIA[®], 4% placebo), hypertension (5% CIMZIA[®], 2% placebo), nasopharyngitis (5% CIMZIA[®], 1% placebo), back pain (4% CIMZIA[®], 1% placebo), pyrexia (3% CIMZIA[®], 2% placebo), pharyngitis (3% CIMZIA[®], 1% placebo), rash (3% CIMZIA[®], 1% placebo), acute bronchitis (3% CIMZIA[®], 1% placebo), fatigue (3% CIMZIA[®], 2% placebo). Hypertensive adverse reactions were observed more frequently in patients receiving CIMZIA[®] than in controls. These adverse reactions occurred more frequently among patients with a baseline history of hypertension and among patients receiving concomitant corticosteroids and non-steroidal anti-inflammatory drugs. Patients receiving CIMZIA[®] 400 mg as monotherapy every 4 weeks in RA controlled clinical trials had similar adverse reactions to those patients receiving CIMZIA[®] 200 mg every other week. The proportion of patients who discontinued treatment due to adverse reactions in the controlled clinical studies was 5% for CIMZIA[®] and 2.5% for placebo.

The safety profile for patients with Psoriatic Arthritis (PsA) treated with CIMZIA[®] was similar to the safety profile seen in patients with RA and previous experience with CIMZIA[®].

The safety profile for AS patients treated with CIMZIA[®] was similar to the safety profile seen in patients with RA.

For full prescribing information, please visit www.ucb.com

About CIMZIA[®] in the EU/EEA⁴

CIMZIA[®] in combination with methotrexate (MTX) is approved in the EU for the treatment of moderate-to-severe active RA in adult patients inadequately responsive to disease-modifying antirheumatic drugs (DMARDs) including MTX. CIMZIA[®] can be given as monotherapy in case of intolerance to MTX or when continued treatment with MTX is inappropriate. CIMZIA[®], in combination with MTX, is indicated for the treatment of active psoriatic arthritis in adults when the response to previous DMARD therapy has been inadequate. CIMZIA[®] can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. CIMZIA[®] is also approved in the EU for the treatment of adult patients with severe active axial spondyloarthritis (axSpA) comprising:

Ankylosing spondylitis (AS) - adults with severe active AS who have had an inadequate response to, or are intolerant to non-steroidal anti-inflammatory drugs [NSAIDs]).

Axial spondyloarthritis (axSpA) without radiographic evidence of AS - adults with severe active axSpA without radiographic evidence of AS but with objective signs of inflammation by elevated C-reactive protein (CRP) and/or Magnetic Resonance Imaging (MRI), who have had an inadequate response to, or are intolerant to NSAIDs.

Important Safety Information about CIMZIA® in the EU/EEA

CIMZIA® was studied in 4,049 patients with rheumatoid arthritis (RA) in controlled and open label trials for up to 92 months. The commonly reported adverse reactions (1-10%) in clinical trials with CIMZIA® and post-marketing were viral infections (includes herpes, papillomavirus, influenza), bacterial infections (including abscess), rash, headache (including migraine), asthenia, leukopenia (including lymphopenia, neutropenia), eosinophilic disorder, pain (any sites), pyrexia, sensory abnormalities, hypertension, pruritus (any sites), hepatitis (including hepatic enzyme increase), injection site reactions, and nausea. Serious adverse reactions include sepsis, opportunistic infections, tuberculosis, herpes zoster, lymphoma, leukaemia, solid organ tumours, angioneurotic oedema, cardiomyopathies (includes heart failure), ischemic coronary artery disorders, pancytopenia, hypercoagulation (including thrombophlebitis, pulmonary embolism), cerebrovascular accident, vasculitis, hepatitis/hepatopathy (includes cirrhosis), and renal impairment/nephropathy (includes nephritis). In RA controlled clinical trials, 4.4% of patients discontinued taking CIMZIA® due to adverse events vs. 2.7% for placebo.

CIMZIA® is contraindicated in patients with hypersensitivity to the active substance or any of the excipients, active tuberculosis or other severe infections such as sepsis or opportunistic infections or moderate-to-severe heart failure.

Serious infections including sepsis, tuberculosis and opportunistic infections have been reported in patients receiving CIMZIA®. Some of these events have been fatal. Monitor patients closely for signs and symptoms of infections including tuberculosis before, during and after treatment with CIMZIA®. Treatment with CIMZIA® must not be initiated in patients with a clinically important active infection. If an infection develops, monitor carefully and stop CIMZIA® if infection becomes serious. Before initiation of therapy with CIMZIA®, all patients must be evaluated for both active and inactive (latent) tuberculosis infection. If active tuberculosis is diagnosed prior to or during treatment, CIMZIA® therapy must not be initiated and must be discontinued. If latent tuberculosis is diagnosed, appropriate anti-tuberculosis therapy must be started before initiating treatment with CIMZIA®. Patients should be instructed to seek medical advice if signs/symptoms (e.g. persistent cough, wasting/weight loss, low grade fever, listlessness) suggestive of tuberculosis occur during or after therapy with CIMZIA®.

Reactivation of hepatitis B has occurred in patients receiving a TNF-antagonist including CIMZIA® who are chronic carriers of the virus (i.e. surface antigen positive). Some cases have had a fatal outcome. Patients should be tested for HBV infection before initiating treatment with CIMZIA®. Carriers of HBV who require treatment with CIMZIA® should be closely monitored and in the case of HBV reactivation CIMZIA® should be stopped and effective anti-viral therapy with appropriate supportive treatment should be initiated.

TNF antagonists including CIMZIA® may increase the risk of new onset or exacerbation of clinical symptoms and/or radiographic evidence of demyelinating disease; of formation of autoantibodies and uncommonly of the development of a lupus-like syndrome; of severe hypersensitivity reactions. If a

patient develops any of these adverse reactions, CIMZIA[®] should be discontinued and appropriate therapy instituted.

With the current knowledge, a possible risk for the development of lymphomas, leukaemia or other malignancies in patients treated with a TNF antagonist cannot be excluded. Rare cases of neurological disorders, including seizure disorder, neuritis and peripheral neuropathy, have been reported in patients treated with CIMZIA[®].

Adverse reactions of the hematologic system, including medically significant cytopaenia, have been infrequently reported with CIMZIA[®]. Advise all patients to seek immediate medical attention if they develop signs and symptoms suggestive of blood dyscrasias or infection (e.g., persistent fever, bruising, bleeding, pallor) while on CIMZIA[®]. Consider discontinuation of CIMZIA[®] therapy in patients with confirmed significant haematological abnormalities.

The use of CIMZIA[®] in combination with anakinra or abatacept is not recommended due to a potential increased risk of serious infections. As no data are available, CIMZIA[®] should not be administered concurrently with live vaccines. The 14-day half-life of CIMZIA[®] should be taken into consideration if a surgical procedure is planned. A patient who requires surgery while on CIMZIA[®] should be closely monitored for infections.

CIMZIA[®] was studied in 325 patients with active axial spondyloarthritis (axSpA) in a placebo-controlled clinical trial for up to 30 months and in 409 patients with psoriatic arthritis (PsA) in a placebo-controlled clinical trial for up to 30 months. The safety profile for axSpA and PsA patients treated with CIMZIA[®] was consistent with the safety profile in RA and previous experience with CIMZIA[®].

Please consult the full prescribing information in relation to other side effects, full safety and prescribing information. European SmPC date of revision 27th October 2014.

http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/001037/WC500069763.pdf

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For further information, Dermira:

- Robert H. Uhl, Westwicke Partners, Investor Relations, Dermira
T +858.356.5932, Robert.uhl@westwicke.com
- Andrew Guggenhime, Chief Operating Officer and Chief Financial Officer, Dermira
T +650.421.7200, investor@dermira.com

For further information, UCB:

Corporate Communications

France Nivelles,
Global Communications,
UCB
T +32.2.559.9178,
france.nivelles@ucb.com

Laurent Schots,
Media Relations, UCB
T+32.2.559.92.64,
Laurent.schots@ucb.com

Investor Relations

Antje Witte,
Investor Relations, UCB
T +32.2.559.94.14,
antje.witte@ucb.com

Brand Communications

Eimear O'Brien,
Brand Communications, UCB
T +32 2 559 92 71,
eimear.obrien@ucb.com

About Dermira

Dermira (NASDAQ: DERM) is a specialty biopharmaceutical company focused on bringing innovative and differentiated medical dermatology products to dermatologists and their patients. Dermira's portfolio of five product candidates targets significant market opportunities and includes three late-stage product candidates, CIMZIA[®] (certolizumab pegol), in development in collaboration with UCB Pharma S.A. for the treatment of moderate-to-severe plaque psoriasis; DRM04, a topical treatment for hyperhidrosis; and, DRM01, a topical sebum inhibitor for the treatment of acne. Dermira is headquartered in Menlo Park, California. For more information, please visit www.dermira.com.

About UCB

UCB, Brussels, Belgium (www.ucb.com) is a global biopharmaceutical company focused on the discovery and development of innovative medicines and solutions to transform the lives of people living with severe diseases of the immune system or of the central nervous system. With more than 8500 people in approximately 40 countries, the company generated revenue of € 3.4 billion in 2013. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news

Forward looking statements - Dermira

This press release contains forward-looking statements that involve substantial risks and uncertainties, including with respect to planned next steps in the clinical development of our product candidates, timing expectations for the receipt of top-line data from the Phase 3 studies, the desired objectives of the Phase 3 studies and future milestone payments. These statements deal with future events and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from the information expressed or implied by these forward looking statements. Factors that could cause actual results to differ materially include risks and uncertainties such as those relating to the outcomes of our clinical trials, our dependence on third party clinical research organizations, manufacturers and suppliers, our ability to obtain regulatory approval for our product candidates, the costs of our development programs, our ability to obtain necessary additional capital, market acceptance of our potential products, our ability to develop and maintain collaborations and license products and intellectual property, the impact of competitive products and therapies including generics and biosimilars, our ability to manage the growth and complexity of our organization, our ability to maintain, protect and

enhance our intellectual property, and our ability to continue to stay in compliance with applicable laws and regulations. You should refer to the risks set forth in Part II, Item 1A, "Risk Factors" in the Company's Quarterly Report on Form 10-Q and other filings the Company makes with the Securities and Exchange Commission from time to time for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. Furthermore, such forward-looking statements speak only as of the date of this press release. We undertake no obligation to publicly update any forward-looking statements or reasons why actual results might differ, whether as a result of new information, future events or otherwise, except as required by law.

Forward looking statements - UCB

This press release contains forward-looking statements based on current plans, estimates and beliefs of management. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial information, expected legal, political, regulatory or clinical results and other such estimates and results. By their nature, such forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties and assumptions which could cause actual results to differ materially from those that may be implied by such forward-looking statements contained in this press release. Important factors that could result in such differences include: changes in general economic, business and competitive conditions, the inability to obtain necessary regulatory approvals or to obtain them on acceptable terms, costs associated with research and development, changes in the prospects for products in the pipeline or under development by UCB, effects of future judicial decisions or governmental investigations, product liability claims, challenges to patent protection for products or product candidates, changes in laws or regulations, exchange rate fluctuations, changes or uncertainties in tax laws or the administration of such laws and hiring and retention of its employees. UCB is providing this information as of the date of this press release and expressly disclaims any duty to update any information contained in this press release, either to confirm the actual results or to report a change in its expectations. There is no guarantee that new product candidates in the pipeline will progress to product approval or that new indications for existing products will be developed and approved. Products or potential products which are the subject of partnerships, joint ventures or licensing collaborations may be subject to differences between the partners. Also, UCB or others could discover safety, side effects or manufacturing problems with its products after they are marketed. Moreover, sales may be impacted by international and domestic trends toward managed care and health care cost containment and the reimbursement policies imposed by third-party payers as well as legislation affecting biopharmaceutical pricing and reimbursement.