UCB Announces Positive CHMP Opinion for CIMZIA® (certolizumab pegol) in Patients with Moderate-to-Severe Plaque Psoriasis

- CIMZIA® (certolizumab pegol) Phase 3 psoriasis data demonstrated significant and clinically meaningful improvements in biologic-naïve and previously treated patients, with clinical benefit maintained up to one year[1]
- This milestone represents UCB's entry into immuno-dermatology, where there is significant unmet patient need
- This follows a recent European Medicines Agency (EMA) label update for CIMZIA in pregnancy and breastfeeding, making CIMZIA the first anti-TNF for potential use in women during both pregnancy and lactation in its approved indications[2]

Brussels, Belgium – April 27, 6:00 PM CEST – UCB today announced that the European Committee for Medicinal Products for Human Use (CHMP) has recommended approval of a label extension for CIMZIA® (certolizumab pegol), to include a new indication in adult patients with moderate-to-severe plaque psoriasis.[3] CIMZIA is the first Fc-free, PEGylated anti-TNF to receive a positive CHMP opinion for use in moderate-to-severe plaque psoriasis.[3] The European Commission's (EC) endorsement of the CHMP positive opinion for psoriasis is expected in the second quarter of 2018 and would further broaden the clinical value of CIMZIA.

"The Phase 3 clinical development program for CIMZIA in plaque psoriasis demonstrated clinically meaningful improvements in primary efficacy endpoints over a 48-week period, as well as improvements in important patient quality of life measures. The data established the durable clinical benefit of CIMZIA, with all three studies showing that the clinical benefit with CIMZIA was maintained for up to one year. Psoriasis has a significant emotional and physical impact on patients, and there is still a need for new therapies that effectively control skin symptoms over time. The availability of CIMZIA in psoriasis would provide healthcare professionals with an effective, broad spectrum anti-TNF with 10 years of clinical experience to help manage this debilitating condition and improve the quality of patients' lives through durable disease control," said Diamant Thaçi, Professor, MD, Director of the Institute for Inflammatory Medicine, University Hospital Schleswig-Holstein, Campus Lübeck.

"CIMZIA is the first anti-TNF of its kind to receive a CHMP positive opinion for this challenging disease. We look forward to offering patients and their dermatologists a new treatment option, with best-in-class efficacy and two different doses to maximize disease control, achieve clear skin and face the serious quality-of-life challenges that often accompany plaque psoriasis. This new indication is particularly relevant following the CIMZIA label update for pregnancy and breastfeeding, as a significant proportion of patients with moderate to severe plaque psoriasis are women, making CIMZIA an optimal treatment for women of childbearing age," said Emmanuel Caeymaex, Head of Immunology and Executive Vice President, Immunology Patient Value Unit, UCB.

The CHMP positive opinion is based on data from a Phase 3 clinical development program consisting of CIMPASI-1, CIMPASI-2 and CIMPACT. The trials, which enrolled over 1,000 patients, with and without prior treatment experience with biologic products, confirmed the efficacy and safety of CIMZIA in the treatment of adult patients with moderate-to-severe plaque psoriasis.[1] Each of the three studies included an assessment of the percentage of patients who achieved at least 75% or greater disease improvement from baseline as measured by the Psoriasis Area and Severity Index (PASI 75) compared to placebo; within 16 weeks in CIMPASI-1 and CIMPASI-2, and within 12 weeks

in CIMPACT. CIMPASI-1 and CIMPASI-2 also assessed the percentage of patients who achieved at least a two-point improvement on a five-point Physician's Global Assessment (PGA) scale to a final score representing clear or almost clear skin, each compared with placebo, at week 16 as a co-primary endpoint. In all three trials, CIMZIA demonstrated statistically significant improvements for all primary and co-primary endpoints compared to placebo at all treatment doses, and the clinical benefit was maintained through to week 48.[1]

According to the updated label, the recommended starting dose of CIMZIA for adult patients is 400 mg at weeks 0, 2 and 4. After the starting dose, the maintenance dose of CIMZIA for adult patients with plaque psoriasis is 200 mg every 2 weeks. A dose of 400 mg every 2 weeks can be considered in patients with insufficient response.[3]

Additionally, the recent European Medicines Agency (EMA) label update for CIMZIA in pregnancy and breastfeeding, makes CIMZIA the first anti-TNF for potential use in women during both pregnancy and lactation in its approved indications.[2] The update included specific pregnancy and lactation information, based on findings from two first-of-their-kind studies, CRIB and CRADLE, together with pregnancy outcomes data.[2,4,5] Results from the UCB-sponsored CRIB study, a prospective pharmacokinetic study, demonstrated no to minimal placental transfer of CIMZIA from mother to child during pregnancy.[4] Data from CRADLE, a prospective pharmacokinetic study, found minimal transfer of CIMZIA into breast milk during lactation.[5] Both studies included a safety evaluation.[4,5] CIMZIA is also approved for the treatment of psoriatic arthritis (PsA), a frequent co-morbidity of psoriasis patients.[2,6]

About Psoriasis

Psoriasis is a common, chronic inflammatory disease with primary involvement of the skin. The skin condition affects men and women of all ages and ethnicities. Psoriasis signs and symptoms can vary, but may include red patches of skin covered with silvery scales, dry, cracked skin that may bleed and thickened, pitted or ridged nails.[7]

Psoriasis affects nearly three per cent of the population, or approximately 125 million people worldwide.[7] Symptoms vary from person to person, but for those who are more severely affected, psoriasis can have a major impact on their quality of life.[7] As many as 42% of patients with psoriasis will develop PsA,[8,9] 33% will develop metabolic syndrome[10] and approximately 46% are often or always depressed because of their psoriasis.[11] Despite drug development advances in the past decade, patient survey data suggest that moderate-to-severe psoriasis is being undertreated.[12]

In pregnancy, psoriasis can present a number of challenges, with 23% of women experiencing a worsening of symptoms during pregnancy.[13] Multiple studies have shown that psoriasis can contribute to an increased risk of adverse pregnancy outcomes including preterm delivery, low birth weight, spontaneous abortion, caesarean delivery, and babies that are large for gestational age and of higher than average birth weight.[14,15,16] In addition, up to 65% of women with psoriasis experience a worsening of psoriasis symptoms postpartum.[13] Controlling psoriasis before, during and after pregnancy is important for the health of both mother and baby.[17]

About the CIMPASI-1, CIMPASI-2 and CIMPACT Studies[1]

CIMPASI-1, CIMPASI-2 and CIMPACT Phase 3 trials each evaluated the efficacy and safety of CIMZIA (certolizumab pegol, CZP) in adult patients with moderate-to-severe plaque psoriasis. The three trials enrolled approximately 1,000 patients, including patients with and without prior treatment experience with biologic products.

In CIMPASI-1 and CIMPASI-2, at week 16, the response rate for patients who achieved a PASI 75 response was 66.5% and 81.4% for patients receiving CZP 200 mg every two weeks (Q2W), and

75.8% and 82.6% for patients receiving CZP 400 mg every two weeks (Q2W), compared to 6.5% and 11.6% for patients receiving placebo, respectively. In addition, the response rate for patients achieving at least a two-point improvement to a final score of clear or almost clear skin on the PGA scale (PGA 0/1) at week 16 was 47.0% and 66.8% for CZP 200 mg Q2W dose-treated patients, and 57.9% and 71.6% for CZP 400 mg Q2W dose-treated patients, compared to 4.2% and 2.0% for patients receiving placebo, respectively. Responder rates for maintenance of a PASI 75 response to week 48 were 67.2% and 78.7% for patients receiving CZP 200 mg Q2W, and 87.1% and 81.3% for patients receiving CZP 400 mg Q2W, respectively. Responder rates for maintenance of a PGA 0/1 score through to week 48, were 52.7% and 72.6% for patients receiving CZP 200 mg Q2W, and 69.5% and 66.6% for patients receiving CZP 400 mg Q2W, respectively.

In CIMPACT, the response rate for patients who achieved a PASI 75 response at week 12, was 61.3% and 66.7% and among patients receiving CZP 200 mg Q2W and CZP 400 mg Q2W, compared to 5.0% for patients receiving placebo, respectively. In patients who received CZP 200 mg Q2W and were PASI 75 responders at week 16, 80.0% of patients who remained on CZP 200 mg Q2W maintained their response at week 48, and 98.0% of patients who then received CZP 400 mg Q2W from week 16 maintained their response at week 48.

In response to the recognized impact of psoriasis on patient experience, improvements in Dermatology Life Quality Index (DLQI) were also observed in all three trials at week 16, and maintained through to week 48. DLQI is a widely used and recognized quality of life measurement instrument used across several dermatological diseases.

In all three trials, CIMZIA demonstrated statistically significant improvements for all primary or co-primary endpoints compared to placebo at all treatment doses, and the clinical benefit was maintained through to 48 weeks. The adverse event profile across all three trials appears consistent with the known safety profile of anti-TNF therapy and no new safety signals were observed with CIMZIA at any dose over 48 weeks.

About the CRIB Study[4]

CRIB was a pharmacokinetic study assessing the potential level of placental transfer of CZP from pregnant women to their infants. The study followed sixteen women (≥ 30 weeks gestation) who were already receiving CZP 200 mg Q2W or 400 mg Q4W for locally approved indications, including rheumatoid arthritis (RA), psoriatic arthritis (PsA), axial spondylitis (axSpA) or Crohn's Disease (CD). CRIB did not include any patients suffering from psoriasis nor patients treated with a CZP 400 mg Q2W dose. In the EU, CIMZIA is not indicated in CD.

The study found that CZP levels were below the lower limit of quantification in 13 out of 14 infant blood samples at birth, and in all samples at weeks four and eight. One infant had a minimal CZP level of 0.042µg/mL (infant/mother plasma ratio 0.0009%). No anti-CZP antibodies were detected in mothers, umbilical cords, or infants. These data indicate no to minimal placental transfer of CZP from mothers to infants, suggesting lack of in utero fetal exposure during the third trimester.

In CRIB, adverse events experienced by the infants did not show any patterns or clusters of events suggesting a specific safety signal in children. Safety data in the mothers were in line with the known safety profile of CZP and pregnancy profile of these underlying diseases.

About the CRADLE Study[5]

The primary objectives of the CRADLE pharmacokinetic study were to determine the concentration of CZP in human breast milk and the average daily infant dose, an estimation of the daily dose of maternal CZP ingested by the infant over the dosing interval.

The study followed 17 lactating women who were already receiving CZP 200 mg Q2W or 400 mg Q4W suffering from RA, PsA, axSpA or CD. CRADLE did not include any patients suffering from psoriasis nor patients treated with a CZP 400 mg Q2W dose.

Among 137 breast milk samples from 17 mothers, all samples had CZP concentrations that were minimal, less than 3 times the lower limit of quantification and less than 1% of the plasma concentration expected with a therapeutic dose. A post-hoc analysis of the relative infant dose (RID) of CZP in breast milk was calculated and ranged from 0.04% to 0.30%. The RID is a useful parameter for assessing drug safety in breastfeeding and experts consider a RID that is less than 10% to be unlikely of concern to infant wellbeing.

In CRADLE, adverse events in the infants of mothers exposed to CZP were consistent with those occurring in unexposed infants of similar age. Adverse events in mothers exposed to CZP were consistent with the known safety profile of CZP.

About CIMZIA® in the EU/EEA

In the EU, CIMZIA® in combination with methotrexate (MTX) is indicated for the treatment of moderate to severe active RA in adult patients inadequately responsive to disease-modifying anti-rheumatic 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 also indicated for the treatment of severe, active and progressive RA in adults not previously treated with MTX or other DMARDs. CIMZIA has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function, when given in combination with MTX.

CIMZIA, in combination with MTX, is also 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 MTX or when continued treatment with MTX is inappropriate.

CIMZIA is also indicated 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.

About CIMZIA® in Fertility, Pregnancy and Lactation in the EU/EEA

Women of childbearing potential

The use of adequate contraception should be considered for women of childbearing potential. For women planning pregnancy, continued contraception may be considered for 5 months after the last CIMZIA dose due to its elimination rate, but the need for treatment of the woman should also be taken into account (see below).

Pregnancy

Data from more than 500 prospectively collected pregnancies exposed to CIMZIA with known pregnancy outcomes, including more than 400 pregnancies exposed during the first trimester, does not indicate a malformative effect of CIMZIA. However, the available clinical experience is too limited to, with a reasonable certainty, conclude that there is no increased risk associated with CIMZIA administration during pregnancy.

Animal studies using a rodent anti-rat TNFα did not reveal evidence of impaired fertility or harm to the foetus. However, these are insufficient with respect to human reproductive toxicity. Due to its inhibition of TNFα, CIMZIA administered during pregnancy could affect normal immune response in the newborn.

CIMZIA should only be used during pregnancy if clinically needed. Non-clinical studies suggest low or negligible level of placental transfer of a homologue Fab-fragment of certolizumab pegol (no Fc region).

In clinical study 16 women were treated with certolizumab pegol (200 mg every 2 weeks or 400 mg every 4 weeks) during pregnancy. Certolizumab pegol plasma concentrations measured in 14 infants at birth were Below the Limit of Quantification (BLQ) in 13 samples; one was 0.042 µg/ml with an infant/mother plasma ratio at birth of 0.09%. At Week 4 and Week 8, all infant concentrations were BLQ. The clinical significance of low levels certolizumab pegol for infants is unknown. It is recommended to wait a minimum of 5 months following the mother's last CIMZIA administration during pregnancy before administration of live or live-attenuated vaccines (e.g. BCG vaccine), unless the benefit of the vaccination clearly outweighs the theoretical risk of administration of live or live-attenuated vaccines to the infants.

Breastfeeding

In a clinical study in 17 lactating women treated with CIMZIA, minimal transfer of certolizumab pegol from plasma to breast milk was observed. The percentage of the maternal certolizumab pegol dose reaching an infant during a 24 hour period was estimated to 0.04% to 0.30 %. In addition, since certolizumab pegol is a protein that is degraded in the gastrointestinal tract after oral administration, the absolute bioavailability is expected to be very low in a breastfed infant. Consequently, CIMZIA can be used during breastfeeding.

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), asthaenia, leukopaenia (including lymphopaenia, neutropaenia), 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, pancytopaenia, 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 haematologic 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 December 2017.

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

CIMZIA® is a registered trademark of the UCB Group of Companies.

For further information, UCB:

Corporate Communications
France Nivelle,
Global Communications, UCB
T +32.2.559.9178,
france.nivelle@ucb.com

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

Brand Communications
Andrea Christopher,
Immunology Communications, UCB
T +1.404.483.7329,
andrea.christopher@ucb.com

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

Isabelle Ghellynck
Investor Relations, UCB
T+32.2.559.95.88,
Isabelle.ghellynck@ucb.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 in immunology or neurology. With more than 7 500 people in approximately 40 countries, the company generated revenue of € 4.5 billion in 2017. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news

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.

# # #

REFERENCES

[1] UCB data on file.
[2] CIMZIA. Summary of Product Characteristics (SmPC), 2018. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/001037/WC500069763.pdf. Last accessed: 03 April 2018.
[3] European Medicines Agency Committee for Medicinal Products for Human Use (CHMP), 27 April 2018: http://www.ema.europa.eu/docs/en_GB/document_library/Summary_of_opinion/human/001037/WC500248169.pdf.
[4] Mariette X, Förger F, Abraham B, et al. Lack of Placental Transfer of Certolizumab Pegol During Pregnancy: Results from CRIB, a Prospective, Postmarketing, Multicenter, Pharmacokinetic Study. *Ann Rheum Dis.* 2018:77(2):228-233.
[5] Clowse ME, Förger F, Hawng C, et al. Minimal to no transfer of certolizumab pegol into breast milk: results from CRADLE, a prospective, postmarketing, multicentre, pharmacokinetic study. *Ann Rheum Dis.* 2017;76:1890–1896.
[6] Oliveira Rocha B, et al. Psoriasis: classical and emerging comorbidities. *An Bras Dermatol.* 2015;90(1):9–20.
[7] International Federation of Psoriasis Associations. Available at: https://ifpa-pso.com/our-cause// Last accessed 22 February 2018.
[8] Mease PJ and Armstrong AW. Managing Patients with Psoriatic Disease: The Diagnosis and Pharmacologic Treatment of Psoriatic Arthritis in Patients with Psoriasis. *Drugs*. 2014;74(4):423-41.
[9] Gladman DD, Antoni C, Mease P, et al. Psoriatic arthritis: epidemiology, clinical features, course, and outcome. *Ann Rheum Dis*. 2005;64 Suppl 2:ii14-7.
[10] Danielsen K, Wilsgaard T, Olsen AO, et al. Elevated odds of metabolic syndrome in psoriasis: a population-based study of age and sex differences*. *British Journal of Dermatology*. 2015;172:419–427.
[11] Weiss SC, Kimball AB, Liewehr DJ, et al. Quantifying the harmful effect of psoriasis on health-related quality of life. *J Am Acad Dermatol*. 2002;47:512-518.
[12] Lebwohl MG, Bachelez H, Barker J, et al. Patient perspectives in the management of psoriasis: results from the population-based Multinational Assessment of Psoriasis and Psoriatic Arthritis Survey. *J Am Acad Dermatol*. 2014;70(5):871-881.
[13] Murase JE, Chan KK, Garite TJ, et al. Hormonal effect on psoriasis in pregnancy and post partum. *Arch Dermatol*. 2005;141(5):601-606.
[14] Amiri N, et al. Pregnancy comorbidities and outcomes in psoriasis and psoriatic arthritis: a prospective cohort study. *Arthritis Rheum*. 2016;68(suppl 10). Abstract 2443; p3219.
[15] Bobotsis R, Gulliver WP, Monaghan K, et al. Psoriasis and adverse pregnancy outcomes: a systematic review of observational studies. *Br J Dermatol*. 2016;175(3):464-472.
[16] Lima XT, Janakiraman V, Hughes MD, et al. The impact of psoriasis on pregnancy outcomes. *J Invest Dermatol*. 2012;132(1):85-91.
[17] Porter ML, Lockwood SJ, Kimball AB. Update on biologic safety for patients with psoriasis during pregnancy. *Int J Women's Dermatol*. 2017;3(1):21-25.