PRESS RELEASE

Health Canada Approves SKYRIZI™ (risankizumab) for the Treatment of Moderate to Severe Plaque Psoriasis

- *SKYRIZI™*(risankizumab) *is a novel, humanized immunoglobulin monoclonal antibody designed to selectively inhibit IL-23 by binding to its p19 subunit to treat moderate to severe plaque psoriasis*[1] *. IL-23 is a naturally occurring cytokine that is involved in inflammatory and immune responses.*
- *Approval of SKYRIZI™* (risankizumab) *is based on results from clinical studies showing significant improvement in levels of skin clearance after just 16 weeks and at 52 weeks with every 3 month dosing in more than 2000 adult patients* [2-5]

Montreal, Quebec, April 18, 2019 – AbbVie (NYSE: ABBV), a global research and development-based biopharmaceutical company, announced today that Health Canada has approved SKYRIZI™ (risankizumab) for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.

Canadians living with moderate to severe plaque psoriasis were well represented in all four of the pivotal clinical trials leading to Health Canada's approval, showing the Canadian leadership in this clinical development program.

In clinical studies, SKYRIZI™ significantly improved levels of skin clearance after just 16 weeks and maintained clearance at one year (52 weeks).[2-5]

"When treating patients with a chronic disease like psoriasis, it is important to have several options available. With SKYRIZI™, we can simplify their treatment by offering a greater chance of clear skin with a safe and easy three-month dosing regimen. As a dermatologist, this allows me to spend the time I have with my patients on other issues pertaining to their overall health and well-being," said Dr. Melinda Gooderham, Dermatologist from the SKiN Centre for Dermatology in Peterborough, Ontario.

Kathryn Clay, President, Canadian Association of Psoriasis Patients added "Psoriasis is a chronic condition affecting more than one million Canadians and many patients still do not reach their treatment goals or lose response to medication over time so we need options for them. Despite tremendous progress, there is still much to be done as highlighted in our report Treat Psoriasis Seriously."

Stéphane Lassignardie, General Manager, AbbVie Canada added: “We are committed to continuing to find new and better medications that will improve the lives of those living with psoriasis. There are still areas of unmet medical need and we are thrilled that people will be able to access SKYRIZI™.”

SKYRIZI™ received Health Canada approval based on results from four pivotal Phase 3 studies, ultIMMa-1, ultIMMa-2, IMMvent and IMMhance evaluating more than 2,000 patients with moderate to severe plaque psoriasis.[2-5] SKYRIZI™ is part of a collaboration between Boehringer Ingelheim and AbbVie, with AbbVie leading development and commercialization globally.

Highlights from the pivotal Phase 3 program

- In the ultIMMa-1 and ultIMMa-2 studies, SKYRIZI™ I met the co-primary endpoints of sPGA 0/1 and PASI 90 at Week 16 ($p<0.001$).[1,4] After 16 weeks of treatment, 88 percent (ultIMMa-1) and 84 percent (ultIMMa-2) of SKYRIZI™ patients achieved sPGA 0/1 and 75 percent of patients receiving SKYRIZI™ in both studies achieved PASI 90.[2,4,5]

- Among patients with sPGA of 0/1 at Week 28 in the IMMhance study, 87.4% (97/111) maintained response with continued treatment with SKYRIZI™ compared to 61.3% (138/225) with withdrawal (placebo) at Week 52[5].

- SKYRIZI™ demonstrated superiority versus adalimumab in the IMMvent study, with 72 percent of patients achieving PASI 90 compared to 47 percent of patients treated with adalimumab at Week 16 ($p<0.001$).[2,4] Following re-randomization at Week 16, 66 percent of patients who started on adalimumab and switched to SKYRIZI™ achieved PASI 90, compared to 21 percent who continued on adalimumab at Week 44 ($p<0.001$).[2,4] The co-primary endpoints of sPGA 0/1 and PASI 90 at Week 16 were met ($p<0.001$).[2,4, 5]

- SKYRIZI™ was also reported to improve health-related quality of life in Phase 3 studies. In ultIMMa-1 and ultIMMa-2, significantly more patients treated with SKYRIZI™ self-reported a Dermatology Life Quality Index (DLQI) score of 0/1 (no impact on health-related quality of life) at Week 16 (66 percent in ultIMMa-1 and 67 percent in ultIMMa-2) compared with ustekinumab (43 percent in ultIMMa-1 and 47 percent in ultIMMa-2)[2,5]

- The most frequently reported adverse drug reactions through the 16-week placebo-controlled period in the SKYRIZI™ group were upper respiratory tract infections (13%) compared with 10% in the placebo group. Common adverse reactions occurring in ≥ 1% of patients treated with SKYRIZI™ included tinea infections, headache, pruritus, fatigue and injection site reactions.[4, 5]

About AbbVie Care
The AbbVie Care program is designed to provide a wide range of customized services including reimbursement and financial support, pharmacy services, lab work reminders and coordination, personalized education and ongoing disease management support throughout the treatment journey. For more information, consult www.abbviecare.ca.

About AbbVie
AbbVie is a global, research and development-based biopharmaceutical company committed to developing innovative advanced therapies for some of the world's most complex and critical conditions. The company's mission is to use its expertise, dedicated people and unique approach to innovation to markedly improve treatments across four primary therapeutic areas: immunology, oncology, virology and neuroscience. In more than 75 countries, AbbVie employees are working every day to advance health solutions for people around the world. For more information about AbbVie, please visit us at www.abbvie.ca and www.abbvie.com. Follow @abbvieCanada and @abbvie on Twitter or view careers on our Facebook or LinkedIn page.

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