Bristol-Myers Squibb’s Novel, Oral, Selective TYK2 Inhibitor Delivered Significant Skin Clearance in Patients with Moderate to Severe Plaque Psoriasis in Phase 2 Trial

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Efficacy endpoints including ≥75% and 90% reduction in the Psoriasis Area and Severity Index (PASI 75, PASI 90) were achieved following 12 weeks of treatment with ≥3 mg daily of BMS-986165

Data published in New England Journal of Medicine and presented at European Academy of Dermatology and Venerology Congress

Late-stage development program initiated in psoriasis and other immune-mediated diseases

PRINCETON, N.J.--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE:BMY) today announced results from a Phase 2 study of BMS-986165, an investigational oral, selective tyrosine kinase 2 (TYK2) inhibitor, in patients with moderate to severe plaque psoriasis. Efficacy endpoints including ≥75% and 90% reduction in the Psoriasis Area and Severity Index (PASI 75, PASI 90) were achieved following 12 weeks of treatment with ≥3 mg daily of BMS-986165, with a favorable risk-benefit profile.

Nasopharyngitis, headache, diarrhea, nausea and upper respiratory tract infection were the most common adverse events (AEs) reported.

These data were published in the New England Journal of Medicine and presented at the 27th European Academy of Dermatology and Venerology (EADV) Congress in Paris. In addition, data from the Phase 2 study describing biomarker changes and the selectivity of BMS-986165 for TYK2 in relation to clinical responses will be presented at EADV on Sept. 15, during a late-breaker session.

“Moderate to severe psoriasis remains undertreated and many patients struggle with insufficient disease control, leaving a significant need for effective and convenient therapies that can provide a positive impact on patients’ lives,” said Mary Beth Harler, M.D., head of Innovative Medicines Development, Bristol-Myers Squibb. “BMS-986165 is a novel, oral, selective TYK2 inhibitor with a distinct mechanism of action that has the potential to help psoriasis patients control their disease, and is planned for study in a wide spectrum of immune-mediated diseases.”

“Currently, patients with moderate to severe psoriasis have a limited number of oral therapies,” said Dr. Kim Papp, M.D., Ph.D., of ProBity Medical Research in Waterloo, Ontario and lead author of the New England Journal of Medicine publication. “Having a favorable risk-benefit profile and delivering significant skin clearance and improvements in quality of life measures, these data suggest that BMS-986165 may be a promising oral option to help patients control their psoriasis in the future.”

The registrational POETYK (PReogram to Evaluate the efficacy and safety of BMS-986165, a selective TYK2 inhibitor) PSO Phase 3 program for patients with moderate to severe plaque psoriasis is currently enrolling. Phase 2 trials for patients with systemic lupus erythematosus or Crohn's disease are also ongoing.

About IM011-011: A Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Phase 2 Study to Evaluate the Clinical Efficacy and Safety of BMS-986165 in Subjects with Moderate to Severe Psoriasis

This was a multicenter, randomized (1:1:1:1:1), double-blind, placebo-controlled study in adults with moderate to severe psoriasis. The trial randomized 267 patients to receive BMS-986165, a novel oral, selective TYK2 inhibitor, in doses of 3 mg every other day (QOD) (n=44), 3 mg every day (QD) (n=44), 3 mg twice daily (BID) (n=45), 6 mg BID (n=45), 12 mg QD (n=44), and placebo (n=45).
or placebo (n=45). The primary endpoint was PASI 75 at Week 12. Key secondary endpoints included PASI 90 and PASI 100, as well as Dermatology Life Quality Index (DLQI), a quality of life measure.

BMS-986165 achieved PASI 75 in 67%-75% of patients in the 3 mg twice daily and higher dose groups, compared to 7% for placebo at Week 12. PASI 75 response rates were 7% for placebo, 9% for 3 mg QOD (P=0.49 vs. placebo), 39% for 3 mg QD (P<0.001), 69% for 3 mg BID (P<0.001), 67% for 6 mg BID (P<0.001), and 75% 12 mg QD (P<0.001). Efficacy was seen regardless of a patient's prior exposure to biologic therapy. Secondary endpoints included PASI 90 (response rates of 2%, 7%, 16%, 44%, 44%, and 43%, respectively) and complete clearance of lesions (PASI 100; response rates of 0%, 2%, 0%, 9%, 16%, and 25%, respectively). The percentages of patients in whom a static Physicians Global Assessment (sPGA) score of 0 (clear) or 1 (minimal disease) was achieved were 64%-76% in the 3 mg twice daily and higher dose groups compared to 7% in the placebo group. A higher percentage of patients had a DLQI score of 0 or 1, reflecting a normal or near-normal quality of life, in the groups receiving 3 mg of BMS-986165 twice daily (42%), 6 mg twice daily (60%), or 12 mg daily (64%) than in the placebo group (4%).

There were three serious AEs reported in the active groups and two in the placebo group. No serious AEs were reported in the highest dose groups (6 mg twice daily and 12 mg once daily). The frequency of all treatment-emergent AEs were 55%-80% in the active groups and 51% in the placebo group. Nasopharyngitis, headache, diarrhea, nausea and upper respiratory tract infection were the most common AEs reported.

**About BMS-986165 and TYK2**

TYK2, an intracellular signaling kinase, mediates cytokine-driven immune and pro-inflammatory signaling pathways that are critical in the cycle of chronic inflammation central to immune-mediated diseases. TYK2 mediates signaling of IL-23, IL-12, and Type I IFN-driven responses but not cytokine responses mediated by other kinases, such as IL-6, hematopoietic growth factors and the IL-2 family. TYK2 signaling is implicated in the pathophysiology of various immune-mediated diseases including psoriasis, lupus and inflammatory bowel disease.

BMS-986165 is a novel, oral, selective TYK2 inhibitor with a unique mechanism of action distinct from other kinase inhibitors, and is being studied in a wide spectrum of immune-mediated diseases.

**About Bristol-Myers Squibb**

Bristol-Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. For more information about Bristol-Myers Squibb, visit us at BMS.com or follow us on LinkedIn, Twitter, YouTube and Facebook.

**Bristol-Myers Squibb Forward-Looking Statement**

This press release contains “forward-looking statements” as that term is defined in the Private Securities Litigation Reform Act of 1995 regarding the research, development and commercialization of pharmaceutical products. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes and results to differ materially from current expectations. No forward-looking statement can be guaranteed. Among other risks, there can be no guarantee that our TYK2 compound will receive regulatory approval for the indications described in this release. Forward-looking statements in this press release should be evaluated together with the many uncertainties that affect Bristol-Myers Squibb’s business, particularly those identified in the cautionary factors discussion in Bristol-Myers Squibb’s Annual Report on Form 10-K for the year ended December 31, 2017 in our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K. Bristol-Myers Squibb undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

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English

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SBMY announces results of Phase 2 trial in patients with psoriasis at #EADV2018

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