AbbVie and Boehringer Ingelheim announce global collaboration on promising immunology compounds

- Anti-IL-23 antibody now in Phase 3 for psoriasis demonstrated greater efficacy over ustekinumab in Phase 2 clinical studies with a potential for quarterly dosing

- Potential to become best-in-class treatment in psoriasis with additional Phase 2 development in Crohn's disease, psoriatic arthritis and asthma; observed safety profile is consistent with the IL-23 class

- AbbVie also gains rights to an anti-CD-40 antibody currently in Phase 1 development; next steps of clinical development are led by Boehringer Ingelheim

- AbbVie updates 2016 adjusted diluted earnings per share guidance to reflect 2016 Phase 3 development costs

NORTH CHICAGO, Ill. and INGELHEIM, Germany, March 7, 2016 -- AbbVie (NYSE: ABBV) and Boehringer Ingelheim today announced a global collaboration to develop and commercialize BI 655066, an anti-IL-23 monoclonal biologic antibody in Phase 3 development for psoriasis. AbbVie and Boehringer Ingelheim also are evaluating the potential of this biologic therapy in Crohn's disease, psoriatic arthritis and asthma. In addition to the anti-IL-23 antibody, AbbVie gains rights to an anti-CD-40 antibody, BI 655064, currently in Phase 1 development. Boehringer Ingelheim will retain responsibility for further development of BI 655064, and AbbVie may elect to advance the program after completion of certain undisclosed clinical achievements.

"This collaboration positions BI 655066 as AbbVie's lead investigational compound in psoriasis, complementing our robust immunology pipeline," said Michael E. Severino, M.D., executive vice president and chief scientific officer, AbbVie. "Our expertise in developing and commercializing the world's leading biologic, combined with Boehringer Ingelheim's clinical success to-date will enable us to offer patients a new treatment option with the potential to meaningfully improve the standard of care."

"Our Immunology R&D teams have successfully brought forward compounds that have the potential to transform the way immune diseases are treated. I believe the collaboration with AbbVie is the best way to ensure broad access for patients to BI 655066 and BI 655064," said Dr. Michel Pairet, Member of the Board of Managing Directors responsible for R&D nonclinical at Boehringer Ingelheim. "Our company remains strongly committed to establishing immunology as a core area of expertise and building our pipeline and capabilities in this important therapeutic area."

Recent Phase 2 head-to-head study results in patients with moderate-to-severe plaque psoriasis showed that BI 655066 had greater efficacy over ustekinumab[1], a commonly used treatment for this life-impacting skin condition. After nine months, 69 percent of patients with moderate-to-severe plaque psoriasis maintained clear or almost clear skin (PASI 90) with BI 655066 in the higher dose group compared to 30 percent of patients on ustekinumab.[1] Patients also achieved this skin clearance faster (approximately eight weeks versus approximately 16 weeks) and for more than two months longer (≥

32 weeks versus 24 weeks) than those on ustekinumab. In addition, completely clear skin (PASI 100) was maintained after nine months in nearly triple the percentage of patients on BI 655066 compared with ustekinumab (43 percent versus 15 percent).[1]

Additional data obtained from a pre-defined analysis reflecting the primary endpoint at 12 weeks is presented below[1]:

	At 12 weeks	
Treatment (sample size)	**PASI 90 Primary Endpoint**	**PASI 100**
BI 655066 18 mg single dose (n=43)	32.6% (P=0.4667)	14.0% (P=0.6497)
BI 655066 90 mg (n=41)	73.2% (P=0.0013)	41.5% (P=0.0178)
BI 655066 180 mg (n=42)	81.0% (P <0.0001)	50.0% (P=0.0011)
Ustekinumab (n=40)	40.0%	17.5%

P-values versus ustekinumab.
18 mg dose is one-time dose given at Week 0. All other treatments dosed at Week 0, 4 and 16; last observation carried forward analysis of Full Analysis Set

BI 655066 is administered as a subcutaneous injection and was generally well-tolerated in the 12-week treatment portion of the Phase 2 study. Serious adverse events were reported for patients in the BI 655066 18 mg treatment group (7.0 percent) and ustekinumab group (2.5 percent), while there were no serious adverse events in the 90 mg and 180 mg treatment groups. One patient discontinued treatment in the BI 655066 18mg dose group. The most common adverse events across the BI 655066 treatment groups were common cold and headache, at 7.3 – 11.6 percent across the dose groups and 2.4 – 7.0 percent, respectively. The most common adverse events in the ustekinumab group were common cold, injection site pain and redness, sore throat and myalgia; each of which occurred in 5.0 percent of patients.

BI 655066 is in Phase 2 development for Crohn's disease and asthma and is about to enter Phase 2 development for psoriatic arthritis. In addition, Phase 2 data for Crohn's disease will be presented at an upcoming medical meeting.

More than 100 million people suffer from psoriasis, a chronic, systemic, immune-mediated disease.[2] Psoriasis is a chronic skin disease of scaling and inflammation and can result in severe physical discomfort and disability.

Financial Terms
Under the terms of the license agreement, AbbVie will make an initial upfront payment of $595 million. Boehringer Ingelheim will be eligible to receive additional development and regulatory milestone payments and royalties on net sales, the terms of which are not disclosed. In the initial period, the companies will share the responsibility for future development of BI 655066. AbbVie will be solely responsible for commercialization of BI 655066, while Boehringer Ingelheim will retain an option to co-promote the compound in asthma. The companies will also establish a joint Steering Committee for the development as well as the initial commercialization phase.

The transaction is subject to customary closing conditions and clearance under the Hart-Scott-Rodino Antitrust Improvements Act.

AbbVie expects this transaction to be approximately $0.08 dilutive to our ongoing earnings per share in 2016, as a result of ongoing investment in the clinical program for BI 655066, including the Phase 3 program for psoriasis. As a result, AbbVie is updating its 2016 adjusted diluted earnings per share

guidance to $4.82 to $5.02. This updated guidance range reflects adjusted earnings per share growth of nearly 15 percent at the midpoint.

About BI 655066
BI 655066 selectively blocks IL-23, a key protein involved in skin inflammation which has been linked to an overactive immune system, and is one of the key drivers of psoriasis.

NB: BI 655066 is not approved by regulatory authorities and its safety and efficacy is being investigated.

About BI 655064
BI 655064 is an antagonistic anti-CD40 antibody. The CD40-CD40L pathway may play a major role in immune disease such as lupus nephritis, Crohn's disease and ulcerative colitis.

NB: BI 655064 is not approved by regulatory authorities and its safety and efficacy is being investigated.

Boehringer Ingelheim
The Boehringer Ingelheim group is one of the world's 20 leading pharmaceutical companies. Headquartered in Ingelheim, Germany, Boehringer Ingelheim operates globally with 146 affiliates and a total of more than 47,700 employees. The focus of the family-owned company, founded in 1885, is researching, developing, manufacturing and marketing new medications of high therapeutic value for human and veterinary medicine. Social responsibility is an important element of the corporate culture at Boehringer Ingelheim. This includes worldwide involvement in social projects, such as the initiative "Making more Health" and caring for the employees. Respect, equal opportunities and reconciling career and family form the foundation of the mutual cooperation. In everything it does, the company focuses on environmental protection and sustainability. In 2014, Boehringer Ingelheim achieved net sales of about 13.3 billion euros. R&D expenditure corresponds to 19.9 per cent of its net sales.

For more information please visit www.boehringer-ingelheim.com

About AbbVie
AbbVie is a global, research-based biopharmaceutical company formed in 2013 following separation from Abbott Laboratories. The company's mission is to use its expertise, dedicated people and unique approach to innovation to develop and market advanced therapies that address some of the world's most complex and serious diseases. Together with its wholly-owned subsidiary, Pharmacyclics, AbbVie employs more than 28,000 people worldwide and markets medicines in more than 170 countries. For further information on the company and its people, portfolio and commitments, please visit www.abbvie.com. Follow @abbvie on Twitter or view careers on our Facebook or LinkedIn page.

Forward-Looking Statements
Some statements in this news release may be forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995. The words "believe," "expect," "anticipate," "project" and similar expressions, among others, generally identify forward-looking statements. AbbVie cautions that these forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those indicated in the forward-looking statements. Such risks and uncertainties include, but are not limited to, challenges to intellectual property, competition from other products, difficulties inherent in the research and development process, adverse litigation or government action, and changes to laws and regulations applicable to our industry. Additional information about the economic, competitive, governmental, technological and other factors that may affect AbbVie's operations is set forth in Item 1A, "Risk Factors," of AbbVie's 2015 Annual Report on Form 10-K, which has been filed with the Securities and Exchange Commission. AbbVie undertakes no obligation to release publicly any revisions to forward-looking statements as a result of subsequent events or developments, except as required by law.

References

[1]K Papp et al. 2015. Onset and duration of clinical response following treatment with a selective IL-23p19 inhibitor (BI 655066) compared with ustekinumab in patients with moderate-to-severe chronic plaque psoriasis. 24th European Academy of Dermatology and Venereology (EADV) congress, Copenhagen, Denmark, 7-11th October 2015 [Presentation About Psoriasis. National Psoriasis Foundation website. http://www.psoriasis.org/about-psoriasis. Accessed on February 26, 2015.]

[2]About Psoriasis. National Psoriasis Foundation website. http://www.psoriasis.org/about-psoriasis. Accessed on February 26, 2015.

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