Novartis announces FDA Advisory Committee unanimously recommends approval of AIN457 (secukinumab) for patients with moderate-to-severe plaque psoriasis

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- - Biologics License Application (BLA) for secukinumab, a "first-in-class" IL-17A inhibitor, is currently under FDA review with an anticipated action date in early 2015
- - FDA Advisory Committee recommendation based on efficacy and safety outcomes of 10 Phase II/III clinical studies of secukinumab in moderate-to-severe plaque psoriasis
- - Affecting 7.5 million Americans, psoriasis may negatively impact daily life and is associated with increased risk for other chronic illnesses
- - National Psoriasis Foundation survey of 5,600 patients found 52% were dissatisfied with their disease management

EAST HANOVER, N.J., Oct. 20, 2014 /PRNewswire/ -- Novartis announced the Dermatologic and Ophthalmic Drugs Advisory Committee (DODAC) to the US Food and Drug Administration (FDA) today voted 7 to 0 to support the approval of AIN457 (secukinumab), a selective interleukin-17A (IL-17A) inhibitor, for the treatment of moderate-to-severe plaque psoriasis in adult patients who are candidates for systemic therapy (a drug that is absorbed into the bloodstream and distributed to all parts of the body) or phototherapy (light therapy). The DODAC based its recommendation on the safety and efficacy outcomes from 10 psoriasis Phase II/III clinical studies which included nearly 4,000 patients with moderate-to-severe plaque psoriasis.

"Moderate-to-severe psoriasis is a serious condition where patients suffer from skin lesions that cause itching, pain and scaling. There is a need for novel therapies as not all treatments are appropriate or effective in every patient," said Vas Narasimhan, Global Head Development, Novartis Pharmaceuticals. "Today's recommendation is based on the efficacy and safety data put forth in our robust clinical trial program and brings us one step closer to delivering an innovative, new treatment option for people suffering from moderate-to-severe psoriasis. We look forward to working with the FDA as it finalizes its review."

The Phase III clinical program for secukinumab included four placebo-controlled pivotal studies which examined secukinumab 300 mg and 150 mg in patients with moderate-to-severe plaque psoriasis. In these studies, secukinumab met all primary and key secondary endpoints, including Psoriasis Area and Severity Index (PASI) 75 and 90 and Investigator's Global Assessment modified 2011 (IGA mod 2011) 0/1 responses, showing significant skin clearance at Week 12. In addition, a majority of secukinumab-treated patients who achieved PASI 75 response and IGA mod 2011 0/1 at Week 12 maintained the response at Week 52 with continued treatment. PASI measures the redness, scaling and thickness of psoriatic plaques, and the extent of involvement in each region of the body. Treatment efficacy is assessed by the reduction of the score from baseline (i.e., a 75% reduction is known as PASI 75 and a 90% reduction is known as PASI 90). PASI 90 is a higher standard of skin clearance compared to PASI 75.

Currently available data showed no major safety issues. In the pooled analysis of the placebo-controlled

period of the pivotal Phase III studies, the incidence of serious adverse events (SAEs) was low and comparable for both doses of secukinumab and placebo (2.0% for both 300 mg and 150 mg vs. 1.7% for placebo). Commonly reported adverse events (AEs) observed with secukinumab were nasopharyngitis, headache, diarrhea, pruritus (itching), and upper respiratory infection.

Novartis submitted a Biologics License Application (BLA) for secukinumab to the FDA in October 2013 and the FDA action date is expected in early 2015. Additionally, submissions have been made with regulatory authorities in the EU with an expected decision anticipated in late 2014 or early 2015.

"The effects of psoriasis go well beyond the visible impact on the skin and frequently have a negative impact on many aspects of a person's daily life," said Dr. Mark G. Lebwohl, Chair of the Kimberly and Eric J. Waldman Department of Dermatology at the Icahn School of Medicine at Mount Sinai and an investigator in the secukinumab clinical trial program. "Today's recommendation offers the promise of a potential treatment for appropriate patients living with psoriasis, who are eager for new options to help them manage their disease."

According to an analysis of surveys conducted of 5,600 patients by the National Psoriasis Foundation (NPF) between 2003 and 2011, 52% of patients with mild, moderate and severe psoriasis were dissatisfied with their disease management. Of the patients surveyed, some were receiving no treatment (9.4-49.2%) or were undertreated (10.2-55.5%).

About Psoriasis
Affecting 7.5 million Americans, psoriasis is a chronic immune-mediated disease characterized by thick and extensive skin lesions (plaques), which can cause itching, scaling, and pain. Patients reported these symptoms can negatively impact their quality of life, both psychosocially and physically, which makes daily functioning difficult. Additionally, patients with psoriasis are at increased risk for other chronic illnesses.

About AIN457 (secukinumab) and interleukin-17A (IL-17A)
AIN457 (secukinumab) is a first-in-class human monoclonal antibody (mAb), being investigated for diseases that affect the immune system. The first IL-17A inhibitor to be reviewed by the FDA for moderate-to-severe plaque psoriasis, secukinumab has been shown to selectively bind to and neutralize IL-17A, inhibiting the release of pro-inflammatory cytokines (messenger proteins). Detailed results from Phase III studies for arthritic conditions (psoriatic arthritis and ankylosing spondylitis) will be presented later this year.

IL-17A is a key messenger protein involved in the development of plaque psoriasis, and is found in high concentrations in psoriasis skin plaques. Research shows IL-17A plays an important role in driving the body's immune response in disorders such as moderate-to-severe plaque psoriasis and certain arthritic conditions and may represent a new target for investigational therapies.

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time. Nor can there be any guarantee that AIN457 will achieve any particular levels of revenue in the future. In particular, management's expectations regarding AIN457 could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; global trends toward health care cost containment, including ongoing pricing pressures; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; unexpected manufacturing issues; general economic and industry conditions, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Novartis
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Located in East Hanover, New Jersey, Novartis Pharmaceuticals Corporation is an affiliate of Novartis AG, which provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, preventive vaccines, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. In 2013, the Group achieved net sales of USD 57.9 billion, while R&D throughout the Group amounted to approximately USD 9.9 billion (USD 9.6 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 135,000 full-time-equivalent associates and sell products in more than 150 countries around the world. For more information, please visit http://www.novartis.com.

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