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MEDIA RELEASE

May 19, 2017

## **Brodalumab, a novel biologic for people with moderate-to-severe psoriasis, receives positive opinion from European CHMP**

Opinion from CHMP: "On 18 May 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product [brodalumab], intended for the treatment of psoriasis[...]. The benefits with [brodalumab] are its ability to inhibit the inflammation and clinical symptoms associated with psoriasis. The most common side effects are arthralgia, headache, fatigue, diarrhoea, and oropharyngeal pain[...]. The full indication is: [brodalumab] is indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy."

**Ballerup, Denmark:** LEO Pharma today announced that it received a positive opinion from the European Committee for Medicinal Products for Human Use (CHMP) recommending marketing authorisation for brodalumab, a novel biologic treatment for adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy.<sup>1</sup> Brodalumab is the only fully human monoclonal antibody that selectively targets the IL-17 receptor subunit A.<sup>2,3</sup> By binding to the receptor with high affinity, brodalumab effectively blocks the biological activity of several pro-inflammatory IL-17 cytokines, which are important in psoriasis.<sup>3,4</sup> Brodalumab is not currently licensed in the EU.

The positive opinion from the CHMP is supported by data from three clinical trials, AMAGINE-1 (n=661), AMAGINE-2 (n=1831) and AMAGINE-3 (n=1881), with a total of 4,373 patients with moderate to severe psoriasis;<sup>5,6</sup> the largest study population of any new biologic treatment in psoriasis to date.<sup>7,8,9,10,11,12,13</sup> All three studies evaluated the efficacy and safety of different doses of brodalumab compared to placebo.<sup>5,6</sup> AMAGINE-2 and AMAGINE-3 also compared brodalumab to ustekinumab.<sup>5</sup>

Results showed brodalumab offered many patients complete skin clearance (PASI 100) at 12 weeks compared to patients treated with ustekinumab [AMAGINE-2: 44% (n=272) versus 22% (n=65), p<0.001; AMAGINE-3: 37% (n=229) versus 19% (n=58), p<0.001].<sup>5</sup> In AMAGINE-1 83% of patients on brodalumab 210mg achieved PASI 75<sup>†</sup> compared to 3% of patients treated with placebo at 12 weeks [83.3% (n=185) versus 2.7% (n=6), p<0.001] and 76% of patients achieved sPGA<sup>†</sup> success versus 1% of patients treated with placebo [75.7% (n=168) versus 1.4% (n=3), p<0.001].<sup>6</sup> High levels of skin clearance were sustained with continuous brodalumab treatment through week 52.<sup>6,14</sup>

"Brodalumab works by blocking the pro-inflammatory cascade that leads to psoriasis, resulting in normalisation of skin inflammation. In the brodalumab clinical trials, the majority of patients achieve clear or almost clear skin within 3 months of treatment as measured by the psoriasis area and severity index (PASI) 100 or 90. In real terms, this means that patients get to the point where their psoriasis no longer bothers them and this is the ultimate treatment goal," commented Professor Kristian Reich, Dermatologist and

\* PASI 75 is defined as  $\geq 75\%$  improvement in Psoriasis Area and Severity Index score

† sPGA success is defined as patients who achieved a static Physician's Global Assessment 0 or 1

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Principal Investigator of the AMAGINE Phase 3 clinical trials programme for brodalumab, Hamburg, Germany.

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Patients also reported experiencing improved health related quality of life after 4 weeks of treatment with brodalumab. After 12 weeks of treatment, seven in ten patients (72%, n=29/40, p<0.0001) reported psoriasis no longer impaired their health related quality of life, (0/1 DLQI) compared with placebo (5%, n=2/37).<sup>15</sup>

*"It is critical that people with psoriasis have the necessary tools and support to help them get through life as unhindered by their condition as possible and don't feel it controls their life. At LEO Pharma we are committed to improving the lives of people with skin conditions, and this positive opinion from the CHMP takes us one step closer to being able to do exactly that for the people who matter most to us. The evidence for brodalumab demonstrates real promise and we hope that we can provide not only a new treatment option, but also the opportunity to help people living with moderate-to-severe psoriasis to take control of their condition and improve their lives significantly,"* says Kim Domela Kjølner, Executive Vice President of Global Research and Development at LEO Pharma.

Data from the three large randomised, controlled AMAGINE clinical trials, found brodalumab to be well tolerated, with an acceptable safety profile.<sup>6,16</sup> The most common adverse events were arthralgia (joint pain), nasopharyngitis (inflammation of the nose and pharynx), headache, and upper respiratory tract infection.<sup>5</sup>

Cases of suicidal ideation and behaviour, including completed suicide, were reported in the clinical trials programme.<sup>17</sup> A causal association between treatment with brodalumab and increased risk of suicidal ideation and behaviour has not been established.<sup>17</sup> Brodalumab will be supported by post-marketing pharmacovigilance activities to capture and follow up on any reports of safety events.

The CHMP's recommendation will now be referred to the European Commission, which has the authority to approve medicines for use in all EU countries. This announcement follows the approval of brodalumab by the U.S. Food and Drug Administration for plaque psoriasis in February 2017; and the approval by the Japanese Pharmaceuticals and Medical Devices Agency for psoriasis vulgaris, psoriatic arthritis, pustular psoriasis and psoriatic erythroderma in 2016.

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## NOTES TO EDITORS

### About Brodalumab

Brodalumab is the only fully human monoclonal antibody that selectively targets the IL-17 receptor subunit A.<sup>2,3</sup> By binding to the receptor with high affinity, brodalumab effectively blocks the biological activity of several pro-inflammatory IL-17 cytokines, which are important in psoriasis.<sup>3,4</sup> Brodalumab is not currently licensed in the EU.

In July 2016, LEO Pharma entered into a partnership agreement with AstraZeneca granting LEO exclusive licence to develop and commercialise brodalumab in Europe. Outside of Europe, Valeant Pharmaceuticals has global commercial rights for brodalumab except in Japan and certain other Asian countries, where the rights are held by Kyowa Hakko Kirin Co., Ltd.

### About LEO Pharma

LEO Pharma helps people achieve healthy skin. By offering care solutions to patients in more than 100 countries globally, LEO Pharma supports people in managing their skin conditions.

Founded in 1908 and owned by the LEO Foundation, the healthcare company has devoted decades of research and development to delivering products and solutions to people with skin conditions. LEO Pharma is headquartered in Denmark and employs around 5,000 people worldwide.

For more information, visit [www.leo-pharma.com](http://www.leo-pharma.com)

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### About Psoriasis

An estimated 125 million people worldwide live with psoriasis,<sup>18</sup> including nearly 14 million Europeans.<sup>19</sup> While there are several types of psoriasis, of which plaque psoriasis is most common affecting up to 97% of patients, the most frequently reported symptoms include thickening and scaling of the skin, itching and erythema (superficial reddening of the skin, usually in patches).<sup>20</sup>

Psoriasis can be a painful, disabling and stigmatising condition with substantial social and psychological impact on a person's life.<sup>20</sup> Although the systemic nature of psoriasis often remains unrecognised, the inflammatory processes involved may be associated with the development of comorbidities<sup>21</sup> such as cardiovascular and metabolic diseases which are more prevalent in people with moderate-to-severe psoriasis.<sup>22,23</sup> Research shows that people with moderate-to-severe psoriasis have a two to three-fold risk of anxiety, depression and suicidal behaviour compared to the general public.<sup>24</sup> According to the World Health Organization, the burden of living with psoriasis is underestimated and it urges for action to fight stigma and improve treatment.<sup>20</sup>

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