

**MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG****Novartis bolsters innovative dermatology portfolio through acquisition of Ziarco Group Limited**

- *Acquisition to add a once-daily oral H<sub>4</sub> receptor antagonist, ZPL389, to treat atopic dermatitis, commonly known as eczema, to the Novartis industry-leading pipeline*
- *Investigational ZPL389 showed a clinically and statistically significant improvement of eczema lesions, leading to a 50% reduction in EASI score compared to placebo after eight weeks of treatment with a favorable safety profile*
- *Eczema is a chronic, inflammatory skin condition affecting millions of children and adults worldwide<sup>1</sup> with an unmet need for effective and safe oral treatments*

**Basel, December 16, 2016** – Novartis announced today that it has entered into a definitive agreement for the acquisition of Ziarco Group Limited, a privately held company focused on the development of novel treatments in dermatology. This acquisition would add a once-daily oral H<sub>4</sub> receptor antagonist in development for atopic dermatitis (AD), commonly known as eczema, to complement the growing Novartis dermatology portfolio and pipeline. The transaction is subject to customary closing conditions, including regulatory approval. The financial details of this transaction are not disclosed.

Ziarco's lead investigational product, ZPL389, is a potential first-in-class oral treatment for moderate-to-severe eczema. Eczema is a chronic, itchy, inflammatory skin condition found in millions of children and adults worldwide<sup>1</sup>. In addition, it is associated with sleep loss and a significant reduction in quality of life<sup>2</sup>. Currently, no safe, effective, and well-tolerated oral treatments are available for the moderate-to-severe form of this condition.

"There is an unmet need for innovative, effective and safe oral treatment options for people living with eczema," said Vasant Narasimhan, Global Head, Drug Development and Chief Medical Officer, Novartis. "We are proud of our dermatology capabilities shown by the recent successful launches of Cosentyx and Xolair. Now we're excited about a potential new medicine for people with eczema through the acquisition of Ziarco and the addition of a first-in-class oral H<sub>4</sub> receptor antagonist to our growing pipeline."

In a proof of concept study, ZPL389 showed a clinically and statistically significant reduction of eczema. After eight weeks of treatment, the compound reduced the Eczema Area and Severity Index (EASI) score by 50% (placebo: 27%, (p=0.01)) in a study of 98 patients. In addition, there was a statistically significant improvement in SCORing Atopic Dermatitis (SCORAD) and body surface area (BSA) scores affected by eczema for ZPL389. The study also showed a decrease in itching, which was numerically greater in the active treatment arm. Both the EASI and SCORAD sub-scores related to itching showed positive results and there was a statistically significant decrease in sleep loss for the active comparator. Itch is a major cause for sleep loss in eczema patients<sup>2</sup>. In clinical studies conducted to date, ZPL389 has a favorable safety profile.

Eczema poses a significant burden on health-care resources and patients' quality of life with recent data showing that its prevalence is still increasing<sup>3</sup>. Eczema affects up to 10% of the population in the US alone<sup>4,5</sup>, with approximately 15% of children and 70% of adults having the moderate-to-severe form of the disease<sup>6</sup>. Treatment does not cure eczema but can control symptoms and potentially improve quality of life<sup>7</sup>.

#### **About the Novartis dermatology portfolio**

Novartis is committed to addressing the unmet medical needs of patients living with dermatological conditions and improving their overall quality of life by providing innovative medicines. The Novartis Dermatology portfolio includes Cosentyx (secukinumab) for the treatment of moderate-to-severe psoriasis and Xolair (omalizumab) for the treatment of chronic spontaneous urticaria.

#### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by words such as "to add," "to treat," "pipeline," "investigational," "agreement for the acquisition," "would," "subject to customary closing conditions," "potential," "excited," "committed" or similar terms, or by express or implied discussions regarding potential completion of the announced acquisition of Ziarco Group Limited, or regarding potential marketing approvals for ZPL389, or regarding potential future revenues from ZPL389 and the other products in the Novartis dermatology portfolio. You should not place undue reliance on these statements. Such forward-looking statements are based on the current beliefs and expectations of management regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that the proposed acquisition will be completed in the expected form or within the expected time frame or at all. Nor can there be any guarantee that Novartis will be able to realize any of the potential strategic benefits, synergies or opportunities as a result of the acquisition. Neither can there be any guarantee that ZPL389 will be submitted or approved for sale in any market, or at any particular time. Nor can there be any guarantee that ZPL389 or the other compound in the Novartis dermatology portfolio will be commercially successful in the future. In particular, management's expectations regarding ZPL389 could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally, including an unexpected failure to obtain necessary government approvals for the acquisition of Ziarco Group Limited, or unexpected delays in obtaining such approvals; the potential that any other closing conditions for acquisition of Ziarco Group Limited might not be met; the potential that the strategic benefits, synergies or opportunities expected from the acquisition of Ziarco Group Limited may not be realized or may take longer to realize than expected; the uncertainties inherent in research and development, including unexpected clinical trial results and additional analysis of existing clinical data; the company's ability to obtain or maintain proprietary intellectual property protection; general economic and industry conditions; competition in general; global trends toward health care cost containment, including ongoing pricing pressures; unexpected safety, quality or manufacturing issues, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. 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**

Novartis 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 and cost-saving generic pharmaceuticals. Novartis is the only global company with leading positions in these areas. In 2015, the Group achieved net sales of USD 49.4 billion, while R&D throughout the Group

amounted to approximately USD 8.9 billion (USD 8.7 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 118,000 full-time-equivalent associates. Novartis products are available in more than 180 countries around the world. For more information, please visit <http://www.novartis.com>.

Novartis is on Twitter. Sign up to follow @Novartis at <http://twitter.com/novartis>  
For Novartis multimedia content, please visit [www.novartis.com/news/media-library](http://www.novartis.com/news/media-library)  
For questions about the site or required registration, please contact [media.relations@novartis.com](mailto:media.relations@novartis.com)

## References

1. Bieber T. Atopic Dermatitis. *N Engl J Med*. 2008;358:1483-1494
2. Patel T. *et al*. Nocturnal Itch: Why do we itch at night? *Acta Derm Venereol*. 2007;87:295-298
3. Nutten S. Atopic Dermatitis: Global Epidemiology and Risk Factors. *Ann Nutr Metab*. 2015;66(suppl 1):8-16
4. Silverberg *et al*. Adult eczema prevalence and associations with asthma and other health and demographic factors: A US population-based study. *J Allergy Clin Immunol*. 2013; 132 (5): 1132-1138.
5. Shaw TE, Currie GP, Koudelka CW, Simpson EL. Eczema Prevalence in the United States: Data from the 2003 National Survey of Children's Health. *J. Invest. Dermatol*. 2001; 131:67-73.
6. Hanifin JM, Reed ML. A population-based survey of eczema in the United States. *Dermatitis*. 2007;18(2):82-91.
7. American Academy of Dermatology (AAD) website. Atopic Dermatitis. Available at: <https://www.aad.org/public/diseases/eczema/atopic-dermatitis#treatment>. Last accessed December 2016

###

## Novartis Media Relations

Central media line: +41 61 324 2200  
E-mail: [media.relations@novartis.com](mailto:media.relations@novartis.com)

Eric Althoff  
Novartis Global Media Relations  
+41 61 324 7999 (direct)  
+41 79 593 4202 (mobile)  
[eric.althoff@novartis.com](mailto:eric.althoff@novartis.com)

Bhavin Vaid  
Novartis Global Pharma Communications  
+41 61 324 8175 (direct)  
+41 79 792 7510 (mobile)  
[bhavin.vaid@novartis.com](mailto:bhavin.vaid@novartis.com)

## Novartis Investor Relations

Central investor relations line: +41 61 324 7944  
E-mail: [investor.relations@novartis.com](mailto:investor.relations@novartis.com)

Central		North America	
Samir Shah	+41 61 324 7944	Richard Pulik	+1 212 830 2448
Pierre-Michel Bringer	+41 61 324 1065	Sloan Pavsner	+1 212 830 2417
Thomas Hungerbuehler	+41 61 324 8425		
Isabella Zinck	+41 61 324 7188		