

HEXIMA LIMITED

ASX ANNOUNCEMENT



2 December 2021

NANCY SACCO APPOINTED CHIEF DEVELOPMENT OFFICER

Global clinical development and operations experience, Peter Welburn to continue as retained consultant

MELBOURNE, AUSTRALIA (2 December 2021): Hexima Limited (ASX:HXL) a clinical stage biotechnology company developing pezadeftide (formerly HXP124) as a potential new prescription topical treatment for onychomycosis, today announces the appointment of Dr Nancy Sacco, PhD as Chief Development Officer. Dr Sacco will report to Michael Aldridge, Managing Director & CEO.

Dr Sacco brings over 20 years of strong leadership experience in the pharmaceutical industry, driving business objectives, including non-clinical discovery, late-stage clinical development, registration, and approval of a range of important pharmaceutical products. Dr Sacco holds a PhD from West Virginia University School of Medicine.

Prior to this appointment, Dr Sacco held Vice President and Head of Clinical Development roles at Xentria, Inc. and AnaptysBio, Inc., overseeing programs with monoclonal antibodies for rare and dermatologic diseases.

In addition, Dr Sacco held executive leadership positions at Revance Therapeutics, Inc. and Avexis, Inc (now Novartis), overseeing clinical operations including the initiation and completion of pivotal studies evaluating safety and efficacy of innovative products (proprietary neurotoxin Daxibotulinum and AVV9 gene therapy ZolgenSMA, respectively).

Dr Sacco has also held roles of increasing responsibilities at P&G Healthcare (Actonel), Pfizer (Lyrice), Astellas (Myrbetriq and Xtandi) and Takeda (Rozerem and ACTOS).

In Dr Sacco's role at Hexima, she will be a senior U.S.-based Hexima representative and will lead the implementation of Hexima's development strategy and clinical development program. Dr Sacco will also be charged with representing the Company at FDA meetings and with other international regulators, and in interactions with scientific advisors, Key Opinion Leaders, and data review committee members.

Hexima's current Chief Development Officer Dr Peter Welburn will remain involved with the Company as a retained consultant to Hexima with specific responsibility for Hexima's toxicology program and expanding Hexima's product pipeline into new therapeutic areas.

Michael Aldridge, Managing Director & CEO said, "We are very pleased to have Dr Sacco join the Hexima team. Her extensive and world-class experience in late-stage clinical development, particularly in dermatology both with US-based and global operations, is a perfect platform for our growth and development plans.

"The team at Hexima is looking forward to working with Dr Sacco as we move closer to announcing the results of our phase IIb clinical trial in Q2 2022, and in our preparations for commencing our phase III program."

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Commenting on her appointment, Dr Sacco said “I am very excited to be joining the Hexima team as pezadeftide moves into this critical phase of clinical development. Moving forward with FDA discussions and initiating the pivotal clinical studies becomes so important for patients seeking a new treatment for onychomycosis.”

-ENDS-

This announcement is authorised for release to ASX by Michael Aldridge, Managing Director & CEO.

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ABOUT HEXIMA

Hexima (ASX:HXL) is a clinical stage, anti-infectives focused biotechnology company engaged in the research and development of defensin peptides for applications as human therapeutics. Our lead product candidate, pezadeftide (HXP124) applied in a topical formulation, is a potential new prescription treatment for toenail fungal infections (or onychomycosis). Hexima is currently conducting an Australian phase IIb clinical trial testing pezadeftide for the treatment of onychomycosis. Hexima holds granted, long-life patents protecting pezadeftide in major markets globally. For additional information please visit www.hexima.com.au. You can also find us on [Twitter](#) and [LinkedIn](#) or email us at info@hexima.com.au.

ABOUT ONYCHOMYCOSIS

Onychomycosis is a common fungal nail infection in the nail plate and nail bed. Prevalence of onychomycosis has been estimated at between 10% (Japan) and 13.8% (USA).¹ Onychomycosis is an infectious disease and is difficult to treat with a significant healthcare burden. It causes pain in approximately 50% of patients and in the US results in close to four doctor's visits annually for treatment.² Onychomycosis impacts a patient's quality of life with 51% unable to wear the shoes they would prefer and 66% distressed by the appearance of their nail.³ It is important to treat onychomycosis as the fungi in the nail can be a source of secondary infection in other areas of the body or infect family members and spread to the environment.

Onychomycosis is the most common nail disorder accounting for 50% of all nail diseases. It is particularly prevalent in older, diabetic and immune compromised populations.² The global market for treatments for onychomycosis was approximately US\$3.7 billion in 2018.⁴

TREATMENT OF ONYCHOMYCOSIS

Approved prescription therapies for onychomycosis comprise either oral or topical medications. Oral medications are associated with adverse effects such as nausea, taste disturbance, and flatulence. They can also severely impact liver function and so often require liver function monitoring. The clinical and commercial success of topical medications has been constrained by an inability of anti-fungal agents to



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effectively penetrate the human nail and the lack of sufficient anti-fungal activity when in contact with the target pathogen.⁵

HEXIMA'S APPROACH

Hexima embraces the significant challenge of new product development for onychomycosis. Hexima has taken a very different approach, building on its many years of ground-breaking research into the evolutionary tools that plants use naturally to fight fungal infections. The result is pezadeftide, a new topical treatment for onychomycosis, with a novel and powerful fungicidal mode of action.

Historically, therapies for onychomycosis have generally focused on new forms of the azole class of antifungal agents or improving the topical delivery of systemic antifungal agents. Hexima's technology is a completely novel approach with fundamental differences that address the well-documented limitations of these traditional technologies.

Pezadeftide penetrates the nail more effectively than existing topical treatments and so can more readily target the fungal cells which proliferate in the nail bed. It is also more effective at rapidly killing fungal cells on contact. Together, these properties mean that pezadeftide has the potential to resolve the fungal infection more quickly, leading to faster and more complete clearing of the infected nail area. Consequently, pezadeftide offers the promise to capture significant value in a large and poorly served market.

¹ Tatchibana et al., Journal of Fungi, 2017

² Joseph et al, Supplement to Podiatry Today, 2013

³ Milobratovic et al., Mycoses, 2013

⁴ Persistence Market Research 2018

⁵ Wang et al., Onychomycosis: Diagnosis and Effective Management, 2018