Press release

Boehringer Ingelheim announces plans to advance potential new treatment for Geographic Atrophy, following positive Phase I results

Ingelheim, Germany and Basel, Switzerland, September 5, 2024 – Boehringer Ingelheim and CDR-Life today announce positive results from the Phase I evaluation of BI 771716 (Study Record | ClinicalTrials.gov), an investigational antibody fragment developed to preserve vision in people living with geographic atrophy (GA). BI 771716 met its primary safety endpoint following intravitreal administration of single and multiple doses. Preparation for the Phase II trial is now underway, with an expected start date in early 2025.

GA is an advanced and severe form of late-stage, dry age-related macular degeneration (AMD), a chronic and progressive retinal disease, that can lead to irreversible and permanent vision loss.[1] It is a leading cause of blindness, affecting more than five million people worldwide, of which more than 40% are considered blind.[1-3] Vision loss associated with GA severely impacts the independence, mental health and quality of life of those living with the condition.[4] Current treatments have limited efficacy and availability.

BI 771716, developed by Boehringer Ingelheim with technology licensed from CDR-Life, is a highly specific antibody fragment, possibly enabling an optimized penetration through all retinal layers to the most critical target site driving GA disease pathology. Based on its molecular properties, BI 771716 has the potential to achieve unprecedented efficacy.

“We are delighted to have achieved a critical milestone in our development of BI 771716, and are now preparing a Phase II clinical study to investigate efficacy and dosing,” said Heiko Niessen, Ph.D., Global Therapeutic Area Head Translational Medicine & Clinical Pharmacology Retinal Health at Boehringer Ingelheim. “BI 771716 is part of our comprehensive retinal portfolio demonstrating our long-term commitment to preserving both eyesight and quality of life in people with retinal diseases.”

"Reaching this safety milestone is a significant step forward for this compound, highlighting the strength of our partnership with Boehringer Ingelheim," said Christian Leisner, Ph.D., Chief Executive Officer at CDR-Life. "Having successfully met all four planned milestones so far, we're optimistic about the continued development of this innovative antibody fragment-based therapy and its potential to provide clinical benefit in geographic atrophy."

“The development of new therapies for geographic atrophy remains one of the most important needs in the age related macular degeneration space,” said Charles C. Wykoff, MD, Ph.D., Principal Investigator of the Phase I trial, Director of Research at Retina Consultants of Texas; Chair of Research, Retina Consultants of America; and Deputy Chair of Ophthalmology for the Blanton Eye Institute, Houston Methodist Hospital. “Achieving the Phase I safety

Reinhard Malin
Sr. Lead, IU Communications
T +49 (1234) 56-789 012
F +49 (1234) 56-789 111
Reinhard_Malin@boehringer-ingelheim.com

Boehringer Ingelheim
Binger Str. 173
55218 Ingelheim am Rhein

More information
boehringer-ingelheim.com

Life forward

endpoint is a meaningful step forward for this potential new treatment for people with this sight-threatening and life-affecting condition."

CDR-Life and Boehringer Ingelheim announced their collaboration and licensing agreement in May 2020, followed by the selection of an antibody fragment-based therapeutic candidate in September 2021. The companies have executed on all milestones to date.

Notes to Editors:

About the trial (NCT06006585) Study Record | ClinicalTrials.gov
The Phase I trial measured the safety, tolerability, and pharmacokinetics of intravitreal single rising doses and multiple doses of BI 771716 in patients with geographic atrophy aged 50+. The purpose of the study was to determine how well different doses of BI 771716 are tolerated.

This study had two parts.

Single rising dose (SRD)
Participants received one injection of BI 771716 directly into one of the eyes affected by geographic atrophy. The primary endpoint was the number of patients with ocular dose-limiting events (DLEs) from drug administration until Day 8; secondary endpoints included occurrence of any ocular adverse events (AEs) and maximum serum concentration of BI 771716 after a single intravitreal (IVT) dose (Cmax).

Multiple dose (MD)
Participants received two injections of BI 771716 directly into the eye. There were 4 weeks between the first and the second injection.

Detailed study results will be made available in the coming months.

About BI 771716
BI 771716, developed by Boehringer Ingelheim with technology licensed from CDR-Life, is a highly specific antibody fragment, enabling an optimized penetration through all retinal layers to the most critical target site driving GA disease pathology. BI 771716 is part of Boehringer Ingelheim's research and development portfolio in retinal conditions.

About Geographic Atrophy (AMD)
AMD is an age-related disease of the central portion of the retina (the macula) which is responsible for high visual acuity that allows for color vision, reading and facial recognition.[4] Geographic atrophy (GA) is an advanced and severe form of AMD that progresses slowly but can lead to permanent vision loss.[4] More than 5 million people worldwide suffer from GA, of which more than 40% are legally blind.[1-3] From age 50 years, the prevalence of GA quadruples every 10 years.[5] Consequently, rising incidences are expected in aging populations.

People with GA experience moderate to severe central vision loss, which can impact daily life activities such as driving, shopping alone, reading, finding street signs and a wide range of social and manual activities that require fine motor control.[4] These limitations can lead to a loss of independence and social isolation, which in turn can have an impact on mental health, leading to depression, fear and anxiety.[4]

About Boehringer Ingelheim
Boehringer Ingelheim is working on breakthrough therapies that transform lives, today and for generations to come. As a leading research-driven biopharmaceutical company, the company creates value through innovation in areas of high unmet medical need. Founded in 1885 and family-owned ever since, Boehringer Ingelheim takes a long-term, sustainable perspective. More than 53,000 employees serve over 130 markets in the two business units Human Pharma and Animal Health. Learn more at www.boehringer-ingelheim.com.

About CDR-Life
CDR-Life is developing powerful T-cell engagers (TCE) to eradicate hard-to-treat solid tumors. Our integrated antibody-based TCE platform unlocks access to a wide range of cancer antigens. We are leveraging this platform to advance a pipeline of potent and selective TCE therapeutics targeting intracellular and surface tumor antigens. With a team of proven drug development experts and backed by leading cross-Atlantic investors, we are working to empower patients' own immune systems to eliminate tumors.

Boehringer Ingelheim's Intended Audiences Notice
This press release is issued from our Corporate Headquarters in Ingelheim, Germany and is intended to provide information about our global business. Please be aware that information relating to the approval status and labels of approved products may vary from country to country, and a country-specific press release on this topic may have been issued in the countries where we do business.

References
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Media Contacts

Boehringer Ingelheim:

Dr. Reinhard Malin
Boehringer Ingelheim
Corporate Affairs

press@boehringer-ingelheim.com

CDR-Life:
Lauren Arnold
LA Communications
Lauren@LACommunications.net