

Affibody, ACELYRIN, and Inmagene Biopharmaceuticals Announce Data from Global Phase 2 Trial of Izokibep in Patients with Psoriatic Arthritis Presented During EULAR

Solna, Sweden, Los Angeles, USA, and Shanghai, China, June 3, 2022 – ACELYRIN, INC., Affibody AB, and Inmagene Biopharmaceuticals today announced data from a 16-week, global, Phase 2 clinical trial of izokibep in 135 patients with psoriatic arthritis (PsA) presented by Frank Behrens, MD, director of the Center of Innovative Diagnostics and Therapeutics Rheumatology /Immunology at the Goethe University in Frankfurt, Germany and a founding member of the Group of Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA), during a podium session at the 2022 European Alliance of Associations for Rheumatology (EULAR) Congress in Copenhagen.

- Data suggest efficacy over standard of care for the treatment of psoriatic arthritis
- Izokibep was well-tolerated, having a safety profile consistent with previous studies and the IL-17A inhibitor therapeutic class
- Supports hypothesis that izokibep offers greater efficacy with high potency and small size, as well as strategy of evaluating IL-17A inhibition's potential for transformative efficacy across many disease states

The randomized double-blind, placebo-controlled, Phase 2 clinical trial evaluated the safety and efficacy of izokibep dosed 80 mg every two weeks (Q2W) or 40 mg Q2W, versus placebo Q2W, in adult patients with active PsA. The global study assessed various endpoints at 16 weeks including the American College of Rheumatology (ACR) response, the Leeds Enthesitis Index (LEI), the Psoriasis Area and Severity Index (PASI) score and Quality of Life via the Psoriatic Arthritis Impact of Disease (PsAID) questionnaire.

Endpoint	Placebo	Izokibep 80 mg Q2W	Izokibep 40 mg Q2W
ACR50 p-value	13%	52% 0.0006	48% 0.0014
Leeds – Enthesitis 1.) (% LEI=0) p-value for means	10%	88% 0.0003	63% 0.0095
PASI75 2.) p-value	14%	85% <0.0001	83% <0.0001

PsAID (% beyond MCID) p-value	12%	41% 0.0017	31% 0.0418
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- 1.) FAS, observed data for LEI > 0 at baseline – N=43 (32%) – post-hoc analysis
- 2.) FAS, observed data for psoriasis BSA ≥ 3% at baseline – N=74 (55%) – post-hoc analysis

"Psoriatic arthritis is a painful and debilitating inflammatory disease of the peripheral joints, skin, and nails, and it can also affect the spine," said Professor Behrens. "Furthermore, residual enthesal pain and inflammation, which occurs in approximately 60% of patients, is often associated with more severe disease, poorer quality of life and is considered one of the most significant unmet needs of psoriatic arthritis patients. The data presented at EULAR demonstrate there is potential opportunity for increased therapeutic efficacy in joints, enthesal pain and inflammation resolution and improved quality of life, all of which would be meaningful for patients living with psoriatic arthritis."

Izokibep was well-tolerated in the study, having a favorable safety profile consistent with that previously observed for izokibep and the IL-17A inhibitor therapeutic class. The most commonly reported AEs were injection site reaction and injection site erythema, the majority of which was mild.

"The improvements demonstrated in arthritis, psoriasis and enthesitis are exciting relative to responses reported for the current standard of care," observed Professor Peter Taylor, Norman Collison chair of musculoskeletal sciences at the University of Oxford. "Combined with the clinically meaningful improvement in disease-specific quality of life and well-tolerated safety profile, izokibep seems promising for patients living with the painful and debilitating symptoms of psoriatic arthritis, and I am eager to see its continued development for patients."

ACELYRIN holds worldwide rights to izokibep except development and commercialization rights by Inmagene in selected Asian countries, including China, Hong Kong, South Korea, and Taiwan, and excluding Japan. Affibody holds commercialization rights in the Nordic countries.

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About izokibep

To date, more than 300 patients – many for up to three years – have received izokibep, a unique, antibody mimetic, interleukin-17A (IL-17A) inhibitor designed to overcome the limitations of monoclonal antibodies. With high potency and small molecular size, izokibep can reach high drug exposure levels through a single, subcutaneous injection that monoclonal antibodies require IV administration to achieve. Additionally, the small size of izokibep – about one tenth the size of a monoclonal antibody – enables its potential to reach targeted tissues that may otherwise be inaccessible to the much larger monoclonal antibodies.

About Psoriatic Arthritis

Psoriatic arthritis (PsA) is a chronic, immune-mediated inflammatory musculoskeletal condition affecting the peripheral joints, the skin (with psoriasis), the nails, and in approximately 30 percent of individuals, the spine. Left under-treated, PsA leads to chronic joint pain, swelling, and damage with a high potential for permanent disability. Psoriatic arthritis pathology is dominated by pro-inflammatory T-helper (Th-17) cells that lead to over expression of IL-17, IL-23, and TNF cytokines.

About Affibody

Affibody AB is a clinical-stage biopharmaceutical company with a broad product pipeline focused on developing innovative bi- and multi-specific next generation biopharmaceuticals based on its unique proprietary technology platforms: Affibody® molecules and Albumod®. Affibody is a holding of Patricia Industries.

For more information, please visit www.affibody.com

About ACELYRIN

ACELYRIN, INC. is a Los Angeles area-based biopharma company focused on providing patients life-changing new treatment options by identifying, acquiring, and accelerating development and commercialization of promising drug candidates and leveraging its expertise to rapidly advance these medicines to patients.

For more information, please visit www.acelyrin.com

About Inmagene Biopharmaceuticals

Inmagene Biopharmaceuticals, with wholly owned subsidiaries in San Diego, Shanghai, Hangzhou, and Wuhan, is a leading biotech company focused on immunology-related therapeutic areas. Believing in "borderless innovation", the Inmagene team integrates efficient resources worldwide to develop drugs for patients globally. Inmagene is operating twelve "Smart Innovation" programs to create and develop novel drug candidates for the global market.

For more information, please visit www.inmagenebio.com.

Disclaimer

This press release contains forward-looking statements. While Affibody AB, ACELYRIN, INC., and Inmagene Biopharmaceuticals consider the projections to be based on reasonable assumptions, these forward-looking statements may be called into question by numerous hazards and uncertainties, so that actual results may differ materially from those anticipated in such forward-looking statements.

Attachments

[Affibody, ACELYRIN, and Inmagene Biopharmaceuticals Announce Data from Global Phase 2 Trial of Izokibep in Patients with Psoriatic Arthritis Presented During EULAR](#)