

# **Ezra Announces FDA Acceptance of Filing of New Drug Application for EZR-104 for the Treatment of Hypertension and Heart Failure.**

**LITTLE ROCK, AR, January 18, 2017**

Ezra Innovations, LLC (Ezra) today announced that the U.S. Food and Drug Administration (FDA) has accepted its New Drug Application (NDA) for an investigational drug product, EZR-104, for the treatment of hypertension and heart failure. The acceptance of the NDA by the FDA indicates that the application is sufficiently complete to permit a substantive review. The Prescription Drug User Fee Act (PDUFA) goal date for approval of this drug is September 10, 2017.

"The FDA acceptance of our NDA for EZR-104 is an important milestone, and brings us closer to offering patients an attractive alternative treatment option for people in the U.S. with hypertension and heart failure," said Joseph Fix, Ph.D., President and Chief Operating Officer, Ezra. "We continue to evaluate our strategic options for commercialization of EZR-104 in the U.S., which include partnership, internal approaches, or a combination of these."

## **ABOUT EZR-104**

EZR-104 combines a leading angiotensin receptor blocker, valsartan, with patented Rubireten™ delivery technology. This novel formulation is designed to control the release of the active drug throughout the 24-hour dosing period and overcome diminished blood concentrations of the drug when administered with a meal, an effect commonly associated with previously approved forms of valsartan. The 505(b)(2) NDA filed in support of this drug contains clinical data developed by Ezra, including two pharmacokinetic studies and one clinical trial in patients with Stage II Hypertension, and references data from extensive clinical use of valsartan over the past 20 years.

## **ABOUT EZRA**

Ezra Innovations, LLC (Ezra) is a privately-held, specialty pharmaceutical company based in Little Rock, Arkansas. Our Company is engaged in the development and commercialization of highly technical and innovatively formulated brand and generic drug products aimed at improving the quality and accessibility of pharmaceutical therapies. Ezra's suite of proprietary delivery technologies has resulted in several new and abbreviated drug applications filed with the FDA and a robust portfolio of investigational drug candidates currently in development. For more information, visit [www.ezrapharma.com](http://www.ezrapharma.com).

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