



Published on FierceBiotech (<http://www.fiercebiotech.com>)

Kamada Wins FDA Approval for Glassia(TM) - a New Liquid, Ready-to-Use Treatment for Alpha-1 Antitrypsin Deficiency

By Maureen Martino
Created Jul 6 2010 - 11:52am

Kamada Wins FDA Approval for Glassia(TM) - a New Liquid, Ready-to-Use Treatment for Alpha-1 Antitrypsin Deficiency

NESS ZIONA, Israel, Jul 06, 2010 (BUSINESS WIRE) -- Kamada (TASE:KMDA), today announced that the United States Food and Drug Administration (FDA) has approved Glassia(TM) (Alpha 1 Proteinase inhibitor, also known as Alpha-1-Antitrypsin (AAT) for the treatment of Alpha 1 deficiency (AATD). Glassia(TM) is now the first and only liquid Alpha- 1-Proteinase Inhibitor worldwide available liquid, ready to use, Alpha- 1-Proteinase Inhibitor on the market.

The FDA approved Glassia(TM) following review of Kamada's Biological License Application (BLA) submitted in May 2009. The FDA's review included Kamada's clinical development as well as auditing and approving Kamada's manufacturing facility, quality assurance and controls.

David Tsur, Chief Executive Officer of Kamada said, "We are very proud with this achievement. This success belongs to each one of the company's employees. With this unique product, Kamada is able to offer the US Alpha-1 patients a new liquid, ready- to- use drug that may ease their therapy routine and provide an additional high quality product in the US market for the benefit of this community.

We are committed to the Alpha-1 patient community and take great pride in further developments of our second generation product, an inhaled Alpha- 1-Proteinase Inhibitor currently in stage 2-3 clinical development."

John Walsh, President of the US Alpha-1 Foundation congratulated Kamada, "We are delighted to welcome Kamada to the US market. Glassia(TM) offers a new and an innovative therapeutic alternative for our patients and we look forward to the company's entry into our patient community.

About Glassia

Glassia(TM) is a unique, high purity, liquid, ready-to-use liquid Alpha- 1-Proteinase Inhibitor that is indicated for chronic augmentation and maintenance therapy in adults with emphysema due to congenital deficiency of alpha1-proteinase inhibitor, also known as Alpha1-Antitrypsin Deficiency. The product is produced using a patented proprietary chromatographic purification method.

About Kamada

Kamada is a public biopharmaceutical company (TASE: KMDA) developing, producing and marketing a line of specialty life-saving biopharmaceuticals. Licensed and marketed worldwide, several of these specialty therapeutics are currently undergoing advanced clinical trials. Kamada is currently in the process of conducting a clinical trial with its second generation AAT product- an inhaled formula which is currently in a phase 2-3 for the indication of Alpha1-Antitrypsin Deficiency.

Additional information is available at www.kamada.com and on www.myglassia.com

SOURCE: Kamada

Source URL:

<http://www.fiercebiotech.com/press-releases/kamada-wins-fda-approval-glassia-tm-new-liquid-ready-use-treatment-alpha-1-antitrypsi>