Granules Receives USFDA approval for complex, Attention Deficit Hyperactivity Disorder (ADHD) Drug

The generic equivalent of Focalin™ XR will make Granules a strong player in the $556 million* US Market

Hyderabad, India, September 11, 2020: Granules (BSE: 532482 | NSE: GRANULES), a world-leading APIs & Formulations Corporation announced today, its US subsidiary has received marketing approval from the U.S. Health Regulator (FDA) for Dexmethylphenidate HCl extended-release capsules for the treatment of attention-deficit hyperactivity disorder. Granules' capsule product is bioequivalent to the reference listed drug (RLD), Focalin™ XR.

Sharing the exciting news, Priyanka Chigurupati, Executive Director of Granules Pharmaceuticals Inc. said "This approval from Granules Pharmaceuticals Inc, received within 13 months of filing reiterates our strength in the development of complex generics. The approval of Dexmethylphenidate XR, a complex, extended-release C-II product, is a good addition to our portfolio. We will be launching the product in the US market soon."

The drug will be manufactured at the Granules manufacturing facility in Chantilly, Virginia.

Granules now have a total of 30 ANDA approvals from the US FDA (28 Final approvals and 2 tentative approvals).

According to IQVIA Health, Dexmethylphenidate HCl ER Capsules had U.S. sales of approximately $556 million* for the most recent twelve months ending in July 2020.

Focalin™ XR is a trademark of Novartis AG.

About Granules: Granules is a vertically integrated pharmaceutical company, headquartered in Hyderabad, India. A world leading manufacturer of Active Pharmaceutical Ingredients (APIs), Pharmaceutical Formulation Intermediates (PFIs) & Finished Dosages (FDs), Granules markets its products worldwide, in both regulated & semi-regulated markets. With 8 manufacturing plants, including the world's largest PFI facility, our presence spans across 75 countries worldwide.

- As per IQVIA MAT July 2020