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Breckenridge Announces Approval of its ANDA for Teriflunomide Tablets (generic for Aubagio®)

Berlin, Connecticut, September 29, 2021

Breckenridge Pharmaceutical, Inc. announces today that the U.S. Food and Drug Administration has granted approval of its Abbreviated New Drug Application for Teriflunomide Tablets (generic for Aubagio®). This product was developed in collaboration with PharmaZell GmbH, Germany. Breckenridge received final approval for the 7mg and 14mg strengths.   Sanofi Aventis LLC and Breckenridge have entered into a Settlement Agreement that permits Breckenridge to launch its generic teriflunomide product on March 12, 2023. According to industry sales data, Aubagio generated annual sales of approximately $1.9 billion during the twelve months ending July 2021.

About Breckenridge:

Breckenridge Pharmaceutical, Inc., the U.S. subsidiary of Towa Pharmaceutical (Osaka, Japan), markets and distributes quality, cost-effective generic pharmaceuticals in the United States. Our products are developed in our affiliated research and development centers, as well as through strategic partnerships nationwide and around the world. With our dedication to customer service, on-time delivery, reliable supply and quality manufacturing, we improve the health and lives of the patients we and our customers serve.

www.bpirx.com

About Pharmazell:

The PharmaZell Group supplies the pharmaceutical industry with Active Pharmaceutical Ingredients and natural source materials. The Group operates production facilities in Germany, Italy and India and offers a focused portfolio of small molecule APIs combined with Custom Development and Manufacturing Services for the pharmaceutical industry worldwide.

www.pharmazell-group.com

For further information, please contact:

Breckenridge Pharmaceutical, Inc.
Robert Gasparino, Associate Vice President – Business Development
Tel: 860-828-8140
E-mail: rgasparino@bpirx.com

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Breckenridge Pharmaceutical, Inc.
15 Massirio Drive, Suite 201
Berlin, Connecticut 0603
Phone: 860-828-8140 | Fax: 860-882-8140
www.bpirx.com