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Breckenridge Announces Tentative Approval of its ANDA for Dabigatran Etexilate Capsules (generic for Pradaxa®)

Berlin, Connecticut, April 22, 2022

Breckenridge Pharmaceutical, Inc. announces today that the U.S. Food and Drug Administration has granted tentative approval of its Abbreviated New Drug Application for Dabigatran Etexilate Capsules (generic for Pradaxa®). This product development was a collaboration between Towa Pharmaceutical Europe, S.L. coupled with an external contract manufacturing organization. Breckenridge has the three strengths consistent with the brand – 75mg, 110mg, and 150mg. According to industry sales data, Pradaxa generated annual sales of $455 million during the twelve months ending February 2022.

About Breckenridge:
Breckenridge Pharmaceutical, Inc., a subsidiary of Towa Pharmaceutical (Osaka, Japan), partners with manufacturers nationwide and around the world to bring quality, cost-effective generic pharmaceuticals to U.S. patients. With our dedication to customer service, on-time delivery, reliable supply and quality manufacturing, we improve the health and quality of life of the patients we and our customers serve.
www.bpirx.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

**All brand names and trademarks are the property of their respective owners.*

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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