Blomquist & Associates Announces the First Study of Likelihood Time to Regulatory Approval for Investigational Oncology Drugs in the US and Europe.

BOULDER, Colorado — April 26, 2018 — Blomquist & Associates today announces the first study of the Likelihood Time to Approval from key events for investigational oncology drugs in clinical development. This is the first study of its kind evaluating both the *time* to regulatory approval (TTA) from key events, and the *chance* (likelihood) a drug is approved by *certain times* from key events (LTTA) for oncology drugs approved both in the US and Europe. Further, Blomquist & Associates report the first study comparing TTA between the US Food and Drug Administration (FDA) and the European Community (EC) for both initial *and* supplemental approvals for investigational oncology drugs.

When creating risk-based financial forecasts for investigational cancer drugs, there is a need for data about the time to approval from key events and the likelihood time to approval by certain times from key events. Blomquist & Associates' study of data extracted from the LTTA Oncology Database fills this need. Our study fills the gap between data for LOA (likelihood of approval) and for launch curve/peak sales. Analyzing data extracted from the LTTA Oncology Database can help improve the accuracy of risk-based forecasts for investors, as well as business executives, in the pharmaceutical and biotech industries.

Key Findings Include:

- The median TTA from Pivotal Trial Primary Completion Date for all Oncology filings was 11.5 months for FDA approval, significantly faster compared to the median TTA of 17.6 months for EC approval, $p < 0.001$.
- The LTTA at 18 months from Pivotal Trial Primary Completion Date for all Oncology filings was 81.5% for FDA approval, compared to 52.3% for EC approval.
- The median TTA from Pivotal Trial Data Read for all Oncology filings was 10.0 months for FDA approval, significantly faster than the median TTA of 16.5 months for EC approval, $p < 0.001$.
- The LTTA at 18 months from Pivotal Trial Data Read for all Oncology filings was 89.4% for FDA approval, compared to 60.2% for EC approval.
- The median Time between FDA and EC approvals for all Oncology filings was significantly different at 5.2 months, $p<0.001$, in favor of the FDA. This represents a 34% reduction in the delay between FDA and EC approval previously reported.
- 18.5% of Oncology filings were approved *first* by the EC before the FDA.

To read the report, a full version is available for download here.

Data used for this study were extracted from Blomquist & Associates' LTTA Oncology Database Version 1.28, covering FDA and EC approvals for investigational oncology drugs. At the time the study was conducted, the LTTA Oncology Database tracked >80 drugs and >190 investigational oncology indications.

ABOUT LTTA ONCOLOGY DATABASE

The LTTA Oncology Database tracks clinical development and regulatory approvals of investigational oncology drugs to assess the TTA and LTTA by FDA and EC. Presently, the LTTA Oncology Database is available on a consulting basis from Blomquist & Associates. A portal / dashboard to access the LTTA Oncology Database is under development

and is planned to be available on a subscription basis in the future. The Database is populated on a regular basis with updated information from clinical trial records, medical meetings, company press releases, corporate earnings reports and presentations, regulatory filing and approval records, and a broad range of other sources. Where possible, links to the various data sources utilized in creating the specific data records are included in the database at the time of data entry to enable review and validation of sources. The database is presently being updated to include approvals for the Japan MHLW (Ministry of Health, Labor and Welfare). Additional LTTA databases are under development for metabolic and neurology drugs.

ABOUT BLOMQUIST & ASSOCIATES

Blomquist & Associates is a boutique consulting firm in Life Sciences. We advise private equity investors, as well as business executives in the pharma and biotech industries. We employ an evidence-based and data-driven approach to provide actionable information that helps our clients make confident decisions on valuation, forecasting and investments. We offer a broad range of consulting services, including around TTA, LTTA, and risk-based forecasting.

CONTACT

To learn more about the report, the LTTA Oncology database, or our other services, please contact:

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