

BIOBUSINESS BRIEFS

MARKET WATCH

Stock price effects of breakthrough therapy designation

Since 2012, the FDA has awarded 'breakthrough therapy designation' (BTD) to drug candidates in clinical development that aim to treat serious diseases and have shown preliminary evidence of substantial effects. BTD provides sponsors with more frequent regulatory interactions and senior-level involvement during trial design and execution, submission and review. Prior studies have found that the term 'breakthrough' leads the public (*JAMA Intern. Med.* 175, 1856–1858; 2015) and physicians (*JAMA* 315, 1516–1518; 2016) to have over-optimistic views of a drug's efficacy. The effect of BTD on investors' perceptions of recipient firms, however, has not previously been examined.

We conducted an event study to examine the effect of BTD on drug companies' stock prices. In the finance literature, event studies are the preferred

method for determining the response of a stock to a disclosed news event, because they define the abnormal returns that exceed what would have been expected based on the behaviour of the trajectories of the market and the company's stock leading up to the event (*J. Bus. Finan. Account.* 19, 533–553; 1992). This is in contrast to simple calculations of a company's returns versus those of a stock index, which reflect the combined effects of the market, the firm's performance in the absence of the event and the event itself, and therefore do not allow one to specifically attribute excess returns to the news event.

We identified 218 public disclosures of BTDs up to 31 May 2018, which represent more than 80% of the 264 BTDs granted during this period (see Supplementary Box 1). For partnered products, we treated each partner as if it had independently

received the BTD. We excluded non-US and private firms, as well as BTD announcements that coincided with major corporate news, including quarterly earnings and clinical trial results. We divided the BTDs into those granted to pre-commercial companies (lacking any marketed products at the time the BTD was granted) versus commercial firms. For each subset, we calculated the cumulative average abnormal returns (CAARs) for 90 days after the BTD was announced using a 'two-factor' model that accounts for changes in the market (S&P 500) and industry (XBI biotechnology index), with a reference range of –110 to –11 days relative to the date of the BTD announcement. Three firms (two commercial, one pre-commercial) were removed from the analysis because their cumulative abnormal returns fell outside the 99% confidence interval around the mean, leaving 143 BTDs in our final analysis set.

For pre-commercial companies ($N=43$), we found that CAARs rose immediately after the BTD announcement, peaked at +9% at day 3 post-BTD ($P=0.01$; see FIG. 1), and remained statistically significant ($P<0.05$) through day 8, after which they lost statistical significance and declined. By contrast, the stock prices of commercial-stage companies ($N=100$) did not exhibit any statistically significant CAARs during the 90-day period after BTD announcement.

Our results show that investors ascribe very little value, and that only transiently, to BTD announcements from pre-commercial companies and no value to those from commercial firms. So, although drug developers receive significant benefits from BTD, these benefits do not include higher sustained valuations in the US public markets.

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Competing interests

F.S.D. works for Pharmagellan, an advisory firm that provides paid consulting services to pharmaceutical and biotechnology companies in areas related to the topics covered in this article.

Supplementary information

Supplementary information is available for this paper at <https://doi.org/10.1038/d41573-019-00019-6>.

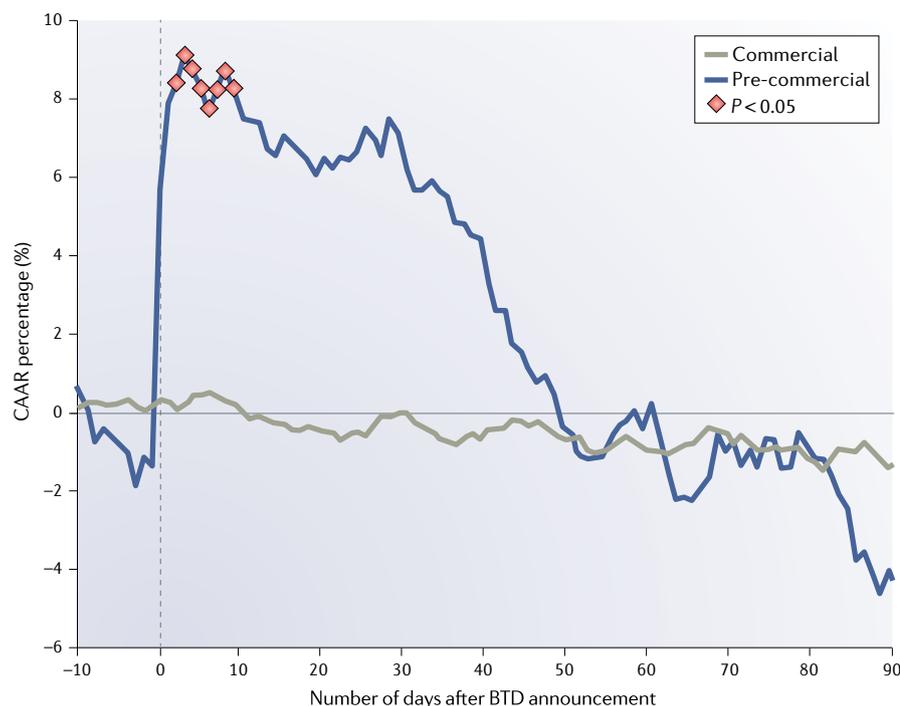


Fig. 1 | **Stock price effects of breakthrough designation.** Cumulative abnormal average returns (CAARs) after breakthrough therapy designation (BTD) announcement for pre-commercial (blue; $N=43$) and commercial (grey; $N=100$) companies, using a two-factor (S&P 500 plus XBI) model; see Supplementary Box 1 for details. The dotted line indicates BTD announcement (day 0). Red diamonds indicate CAARs that are statistically significantly different from 0% at $P<0.05$.