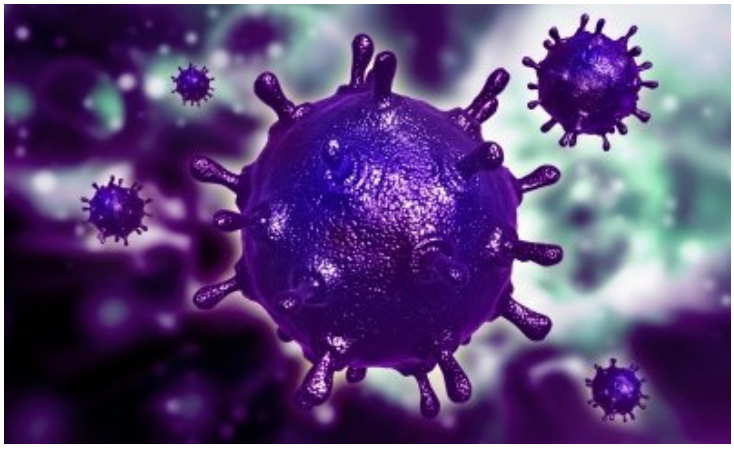
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Boehringer Ingelheim bevacizumab biosimilar candidate demonstrates bioequivalence to Avastin

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Boehringer Ingelheim announced new data from the Phase I INVICTAN-1 study, which show that BI 695502, its bevacizumab biosimilar candidate, is bioequivalent to U.S.-licensed and -EU approved Avastin. (Avastin is an angiogenesis inhibitor that is used to treat a variety of cancers.)

BI 695502 met all the pre-defined primary and secondary endpoints in the INVICTAN-1 study. These data were presented in a poster at the American Association of Pharmaceutical Scientists Annual Meeting in Denver, CO, November 13 - 17.

"Findings from this study are an important step to confirm that BI 695502 is biosimilar to Avastin, and we look forward to the completion of the ongoing pivotal Phase III trial in lung cancer," said Sandeep Athalye, MD, Vice President and Head, Clinical Development and Medical Affairs Biosimilars, Boehringer Ingelheim. "These data show our commitment to develop high-quality therapeutic options for patients with cancer and contribute to the long-term sustainability of global healthcare systems."

About BI 695502 and INVICTAN

BI 695502, a bevacizumab biosimilar candidate to Avastin, is a monoclonal antibody that may slow or stop the growth of certain tumor types by preventing the growth of blood vessels that supply the tumor.1

INVICTAN-1 (NCT01608087) is a randomized, blinded, single-dose, parallel-arm Phase I clinical study, evaluating bioequivalence (how a drug is absorbed, distributed, metabolized and excreted in the body) of BI 695502 to Avastin. The study enrolled 91 healthy male individuals who were randomized evenly across treatment groups. BI 695502 was well-tolerated in this study, with no clinically relevant differences in safety or immunogenicity evaluations between the BI 695502 and bevacizumab treatment groups.2

INVICTAN -2 (NCT02272413) is a randomized, double-blind Phase III study, evaluating efficacy and safety of BI 695502 plus chemotherapy versus Avastin plus chemotherapy in patients with advanced non-squamous non-small cell lung cancer.