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BTG announces positive safety and efficacy data in over 500 DC BeadM1™ patients & compelling health economic data for TheraSphere®

Lisbon, Portugal, 27 September 2015 – BTG plc company (LSE: BTG), announced promising data today for DC BeadM1™, supporting the efficacy and tolerability of doxorubicin-eluting DC BeadM1™ in the treatment of patients diagnosed with liver-confined HCC (hepatocellular carcinoma). The preliminary results of the study, in which patients achieved a median overall survival (OS) of 41 months, were presented during the 2015 CIRSE (Cardiovascular and Interventional Radiological Society of Europe) International Conference in Lisbon, Portugal.

While DC Bead® drug-eluting bead is backed by clinical safety and efficacy data in over 3,000 HCC patients, DC BeadM1™ is a more recent addition to the product range. Designed with a narrow size distribution, so that it can travel deeper into the vasculature of the tumour, while also allowing for a more concentrated drug delivery¹, DC BeadM1™ offers a new standard-of-care and a much more targeted therapy than conventional chemoembolisation for the treatment of HCC.

“Unlike the majority of cancer-types, for which improvements in diagnosis and treatment are set to result in a significant 17% reduction in mortality by 2030, the burden of HCC is continuing to grow, with mortality predicted to increase by 39% over this same time period,” commented Dr Camillo Aliberti from the Istituto Oncologico Veneto, Padua, Italy and lead author of ‘*A Single-Centre, Retrospective, Single-Arm, Open-Label Study of DC BeadM1™ in HCC: Preliminary results*’. “We are always looking for refinements and improvements to the tools we have to optimise outcomes in this challenging patient population.

DC BeadM1™ is a promising new addition to the proven DC Bead® product range and this study is significant in terms of the impressive safety and efficacy results it demonstrates.”



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The single-centre, retrospective, single-arm, open-label study, reviewed the treatment of 547 HCC patients treated with DC BeadM1™ loaded with doxorubicin, between 2013 and 2015. Response, measured using mRECIST (modified Response Evaluation Criteria in Solid Tumors [RECIST] guideline), showed a median overall survival (OS) of 41 months, and a median progression-free survival (PFS) of 15 months. Furthermore, there were no significant treatment-related adverse events (AEs).

Economic evaluation of glass yttrium-90 microspheres versus sorafenib

A second piece of analysis, also presented during CIRSE 2015, looked to evaluate the cost-effectiveness of ⁹⁰Y microspheres (TheraSphere®), a novel radioembolisation therapy that consists of millions of small glass microspheres containing radioactive ⁹⁰Y, versus sorafenib for the treatment of advanced HCC.

The analysis was conducted using the methodological criteria published by NICE². Within the analysis 10-year (lifetime) outcomes were estimated with results showing improvements across all measures for TheraSphere® (Time-To-Progression (TTP) versus sorafenib [6.2 vs. 4.9 months], increased median Overall Survival (mOS) versus sorafenib [13.8 vs. 9.7 months], and increased quality-adjusted life years (QALYs) versus sorafenib [1.12 vs. 0.85 years]). As a result, the total lifetime cost of TheraSphere® treatment (in the UK) was calculated to be significantly lower compared to sorafenib (£21,441 vs. £34,050).

Jane Lapon, BTG VP, Global Market Access (OUS) commented, “This exciting data supports a rapidly developing clinical evidence base for the use of TheraSphere® as an alternative treatment modality in HCC. At a time of global austerity, the analysis also suggests there is potential for it to be a more cost-effective treatment than the current standard-of-care.”

Peter Pattison, BTG General Manager Interventional Oncology, Commercial Operations, “One of the most significant challenges we currently face in healthcare, and no more so than in the area of oncology, is cost effectiveness and affordability for our healthcare systems. This data highlights the potential of alternatives to systemic chemotherapy, to drive improved value and efficiencies.”

-ENDS-

About BTG Interventional Medicine

BTG Interventional Medicine is part of BTG plc, a growing international specialist healthcare company. As medicine moves from major surgery to minor procedure, from the systemic to the local, no company endeavours to do more than BTG Interventional Medicine to help doctors in their quest to see more, reach further and treat smarter. Our growing portfolio of Interventional Medicine products is designed to advance the treatment of liver tumours, advanced emphysema, severe blood clots, and varicose veins. To learn more about BTG Interventional Medicine, please visit: www.btg-im.com

About TheraSphere®

TheraSphere® ⁹⁰Y glass microspheres are specifically engineered to carry far greater power than any other ⁹⁰Y liver-directed cancer therapy, delivering high doses of radiation to liver tumours while sparing normal tissue. The result is a powerful, targeted and well-tolerated therapy that may lead to patients becoming eligible for curative therapies. In the EU, TheraSphere® is CE Marked for the treatment of hepatic neoplasia. For full instructions for use and important safety information, please visit www.therasphere.com.

About DC Bead®

DC Bead® is the only drug-eluting bead with CE Mark approval for loading with doxorubicin and irinotecan, providing an effective standardised liver-directed therapy for primary and metastatic liver cancer. With ten years' clinical experience, extensive peer-review evidence supports the benefits offered by the unique chemistry of DC Bead®. In intermediate HCC, these benefits include improved tolerability and tumour response versus cTACE and high rates of five-year survival.^{1,3-6} In metastatic colorectal cancer patients, DC Bead® has been shown to offer improved survival and enhanced quality of life versus systemic chemotherapy alone.⁷ In the EU, DC BeadM1™ embolic drug-eluting bead is CE Marked and is indicated for loading with irinotecan for the treatment of metastatic colorectal cancer and for loading with doxorubicin for the treatment of malignant hypervascular tumours. For instructions for use and important safety information, please visit www.dcbeadm1.com/ifu.

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