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BRAZILIAN EXPERTS ON ONCOLOGY AND COMPANION DIAGNOSTICS CONVENE TO REVIEW BRAZILIAN HEALTHCARE POLICY FOR TARGETED ONCOLOGY THERAPIES AND COMPANION DIAGNOSTIC TESTING

WASHINGTON, D.C., JULY 26, 2016 --- In November of 2015, the Americas Health Foundation (AHF) convened a panel of six Brazilian experts on oncology and companion diagnostics to review existing barriers and develop practical recommendations concerning policy fixes for the use of companion diagnostics (CDx) and personalized medicines for oncology in Brazil. The consensus conference sought to develop guidelines that could stimulate early collaborations that might result in faster access to promising new treatments for patients with serious and life-threatening diseases.

Companion diagnostics (CDx) are tests being developed to identify patients most likely to benefit from specific treatments based on their own genetic makeup and biology. In the case of oncology, CDx and related pharmacological-based interventions could improve the predictability of the oncology drug development process and become an important tool for oncologists in choosing the optimal treatment for specific patient groups or sub-groups.

The growth of the CDx sector has been significant in the past several years with much of the activity focused in the area of oncology. A number of CDx markers have been developed for targeted therapeutics, as well as to predict toxicity, efficacy and drug dosage to ensure hitting critical endpoints. However, the development of CDx, related pharmacological-based interventions, and drugs requires close collaboration between CDx manufacturers, drug companies and regulatory authorities. Guidelines for CDx and related pharmacological-based interventions are meant to help companies identify the need for diagnostics in the earliest stages of drug development. This way, both the diagnostics and the drugs can be developed simultaneously and patients can have access to both test results and consequently options of treatment.

During the three-day conference, the panelists addressed such issues as the current pathways or procedural steps for oncology companion diagnostics and the corresponding therapies (a) for regulatory approval / licensing and (b) for public/private reimbursement and or pricing; recommendations regarding the clinical use of oncology companion diagnostics; and the benefits of targeted drugs in terms of clinical outcomes and cost in comparison to generalized medicine.

The resulting paper, entitled “Brazilian health-care policy for targeted oncology therapies and companion diagnostic testing,” was published as a policy review on July 27, 2016 in the *Lancet Oncology*. The panel members and authors of this paper are Dr. Carlos Gil Ferreira, D’Or Institute for Research and Education, Rio de Janeiro, Brazil; Maria Isabel Achatz, A C Camargo Cancer Center, São Paulo, Brazil; Patricia Ashton-Prolla, Universidade Federal do Rio Grande do Sul and Hospital de Clínicas de Porto Alegre, Porto Alegre, Brazil; Maria Dirlei Begnami, Hospital A C Camargo, São Paulo, Brazil; Fabricio K Marchini, Laboratório de Genômica Funcional, Fundação Oswaldo Cruz / Instituto Carlos Chagas, Curitiba, Paraná, Brazil; and Stephen Doral Stefani, Mãe de Deus Cancer Center, Porto Alegre, Brazil.

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