para HTLV1. Sorologia para HTLV1 e 2 de esposo foi não reagente. Sorologia de filha foi reagente e imunofenotipagem revelou presença de mais de 5% de linfócitos periféricos CD3+/CD4+/CD25+, compatível com ATLL forma smoldering. Permanece assintomática e em seguimento. Sorologia de filho foi reagente e recusou seguimento. **Discussão:** O HTLV tem distribuição variável, maior prevalência no sul do Japão (10%) e alguns países africanos. Na América do Sul, estima-se que o Brasil tenha o maior número de infectados, sendo Maranhão, Pará, Pernambuco e Bahia os Estados de maior prevalência (6,7-10/1000 habitantes). Como infecção negligenciada, a falta de programa de rastreio populacional nacional implica em seguimento de transmissão e falta de diagnóstico. Provável mecanismo de transmissão da infecção do caso índice para filhos é o vertical. **Conclusão:** Consideração para medidas que visem diagnóstico precoce e difusão de conhecimento da história natural da infecção pelo HTLV1 são medidas fundamentais para controle da infecção pelo HTLV1 e, assim, minimizar complicações potencialmente graves da infecção.

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A RETROSPECTIVE EXTENSION STUDY TO EVALUATE LONG-TERM SAFETY AND EFFICACY OF RITUXIMAB BIOSIMILAR (RTXM83) IN BRAZILIAN PATIENTS WITH DIFFUSE LARGE B-CELL LYMPHOMA

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Introduction: RTXM83 was previously evaluated in a phase 3, prospective, multicenter, randomized study to compare the efficacy, pharmacokinetics (PK), pharmacodynamics (PD), safety, and immunogenicity profile versus reference rituximab as first-line treatment of Diffuse Large B-Cell Lymphoma (DLBCL). The study (ClinicalTrials.gov Identifier: NCT02268045) carried out in twelve countries, including Brazil, established that RTXM83 showed non-inferior efficacy and similar safety and immunogenicity to the reference rituximab, which led to its regulatory approval in Brazil in 2019. However, the phase 3 study did not collect long-term efficacy endpoints, as progression-free survival (PFS) and overall survival (OS). **Objectives:** In addition to phase 3 study, we designed this retrospective extension study to obtain long-term safety and efficacy results for the rituximab biosimilar, and to gather information from phase 3 study in the Brazilian population. **Methodology:** Among 272 patients randomized in the phase 3 study, 28 are Brazilian patients from four regions of Brazil, including the Northeast, Center-West, Southeast, and South. The study enrolled 12 patients in the reference rituximab arm and 16 patients in the RTXM83 arm. To investigate DLBCL endpoints in Brazilian patients, we will perform a subgroup analysis comprising those 28 patients previously randomized in the phase 3 study. The analysis will include patient characteristics, event-free survival (EFS), overall response rate (ORR), and adverse events. To evaluate RTXM83 long-term safety and efficacy endpoints, we will retrospectively collect PFS, OS, and late adverse events during a follow-up of approximately 36 months since the date of randomization in the phase 3 study. Safety profile will include late adverse events of interest as infections, late-onset neutropenia, progressive multifocal leukoencephalopathy, reactivation of hepatitis, intestinal perforation, and secondary neoplasm. All 28 randomized patients from 13 study sites will be eligible for this retrospective extension study once they consent to their data collection and sign the Informed Consent Form. The source data from Brazilian patients will be collected in their respective treatment sites, which agreed to participate in this extension study. We expect to conclude this study in early 2022. **Perspectives and conclusion:** In developing countries like Brazil, the use of biosimilars may result in significant health care savings and patient access to target therapies. Despite that, the adoption of biosimilars in clinical practice is not yet widely accepted among Brazilian physicians. Therefore, we do expect to deliver more scientific data about rituximab biosimilar long-term safety and efficacy endpoints, which may collaborate to expand its use among patients with hematological diseases.

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ATUALIZAÇÃO DO ESTUDO AMBISPECTIVO DO REGISTRO DE LINFOMA DE CÉLULAS-T, NAS CINCO MACRORREGIÕES BRASILEIRAS

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