subtypes (3/9–33.3% and 7/16-43.7%, respectively; p = 0.07). So, the mutation *RHOA* was predominantly found in THf cell-derived neoplasms in our cohort. The mutational status of *DNMT3A*, *RHOA* and *TET2* genes had no prognostic impact on OS, with p = 0.85, p = 0.13 and p = 0.95, respectively. The same was observed in relation to PFS for the *DNMT3A* (p = 0.70) and *TET2* (p = 0.52) mutations. However, the presence of the *RHOA* mutation was associated with the unfavorable PFS in our cohort (HR:1.98, p = 0.05). We observed 2-year PFS of 28.6% (95% CI: 8.8-52.4%) for mutated-*RHOA* cases versus 52.9% (95% CI: 37.3-66.3%) for wild-type-*RHOA* patients (p = 0.05). We also demonstrated that the presence of the *RHOA* mutation was a predictor of lower ORR to first-line therapy (p = 0.01) and was associated with high tumor burden (p = 0.03). **Conclusion:** For the first time we demonstrated the unfavorable prognostic impact of the *RHOA* mutation in patients with nPTCL with THf-phenotype, making it a potential molecular biomarker predictor of poor-PFS, associated with resistance to primary therapy and with high tumor burden.

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RITUXIMAB BIOSIMILAR RTXM83 POST-MARKETING SURVEILLANCE IN BRAZIL: EVALUATION OF THE ADVERSE EVENTS SPONTANEOUSLY REPORTED TO PHARMACOVIGILANCE

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Background: Biosimilars are highly similar to their reference products, but unlike generic drugs, they are not identical. Differences between a biosimilar and its reference product may arise because of the complexity of biologics, differences in the cell lines and processes used during manufacturing. Biosimilars are approved in Europe, United States and Brazil through a regulatory pathway based on comparative analytical, clinical studies and demonstration of no clinically meaningful differences from their reference products. Post marketing pharmacovigilance is a useful tool to confirm the safety profile of biosimilar medication in the general population, outside of controlled environment of clinical studies. In 2019, rituximab biosimilar RTXM83 was approved in Brazil. **Objective:** The purpose of this communication is to present rituximab biosimilar RTXM83 information collected from adverse events (AEs) spontaneous reports during post-marketing pharmacovigilance activities in Brazil. **Method:** Descriptive retrospective study. Treatment related data and AEs from all spontaneous reports with biosimilar rituximab RTXM83 were reviewed. AEs were classified according to medical terminology (MedDRA) and seriousness assessed by the CTCAE (Common Toxicity Criteria) version 5.0 scale. Descriptive analysis of demographic data and AEs reported was performed. **Results:** A total of 32 reports containing 59 adverse events (AEs) were received from spontaneous reports between September 2019 and July 2021. From 32 reports, 19 were female, 12 were male and 1 not informed. The patients mean age was 48,8 (13 to 81years). The treatment indication was hematology oncology diseases in 23 (72%) patients, autoimmune disease in 7 patients (22%) and not informed in 2 (6%) patients. Regarding AEs seriousness and expectedness, 26 (44%) were non-serious AEs (24 expected / 2 unexpected) and 33 (56%) were serious AEs (22 expected / 11 unexpected). The five most frequently reported AEs according to SOC (System Organ Classification) were immune system disorders 19 (32%), blood and lymphatic system disorders 14 (24%), nervous system disorders 4 (7%), investigations 3 (5%), respiratory, thoracic and mediastinal disorders 3 (5%). The five most commonly reported adverse events (MedDRA PT - Preferred term) were infusion related reaction 18 (31%), neutropenia 6 (10%), anaemia 3 (5%), leukopenia 2 (3%), thrombocytopenia 2 (3%). **Conclusion:** AEs spontaneously reported in patients treated with biosimilar rituximab RTXM83 were consistent with the reference safety information based on literature data and the Summary of Product Characteristics (SmPC) of the reference product. No new safety signals were detected.

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SARCOMATOID DIFFUSE LARGE B-CELL LYMPHOMA: A RARE MORPHOLOGICAL VARIANT WITH MULTI-VISCERAL INVOLVEMENT

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Introduction: Diffuse Large B-Cell Lymphoma (DLBCL) is the most frequent subtype of non-Hodgkin's lymphoma (NHL), accounting for 50% of all NHL cases seen at HC-FMUSP. Up to 40-50% of DLBCL cases have extranodal involvement. However, female genital tract involvement is very rare, accounting for less than 0.5% of cases. Spindle/sarcomatoid cell neoplasms usually have mesenchymal histogenesis, however rare cases of aggressive NHL with a spindle-shaped morphological aspect have been recently described, although this variant is still not fully recognized as a specific pathological entity. **Objectives:** To describe a rare case of DLBCL with primary uterine cervix involvement, and sarcomatoid morphological pattern, as well as multi-visceral involvement. We intend to highlight the importance of recognizing this entity in the differential diagnosis of spindle-shaped malignant neoplasms. **Case report:** A 51-year-old woman, with no previous comorbidities, sought medical service at the HC-FMUSP due to a vulvovaginal tumor with progressive growth over the last 12 months. Gynecological examination showed an ulcerated tumor in the cervix, extending to the vaginal cavity and exteriorizing through the vulvar introitus. Computed tomography showed a 7 cm tumor mass in the cervix and pathological bone fracture of the L3 vertebra. A biopsy of the uterine cervix showed atypical fusiform cell proliferation, inferring a diagnosis of uterine leiomyosarcoma. However, bone biopsy showed proliferation of large atypical lymphoid cells,