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Myeloma using statistical methods but also allowed us to predict new patients with missing data. This model was built and tuned using data from multiple myeloma patients from a public database from a study conducted in Arkansas.

Results: The results of the Bayesian model allowed us to estimate the survival of patients with missing information. Additionally, when compared with the classic Cox models in patients with complete data, the performance metrics did not deteriorate (concordance index of 72% and 71% respectively) in patients with complete data. In addition, it allows for estimating survival and staging the risk of patients with multiple myeloma with missing data, maintaining the concordance rate at 71%.

**Conclusions:** A model that performs as well as Cox models in patients with complete data and maintains this performance in patients with missing data is achieved. It also allows the prediction of new patients who are diagnosed with multiple myeloma without the restriction that their complete clinical or genetic data is needed.

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Preliminary results from a phase II study of amulirafusp alfa (IMM0306) in patients with relapsed or refractory CD20positive B-cell non-Hodgkin's lymphoma

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**Background:** Amulirafusp alfa (IMM0306) is a fusion protein of CD20 monoclonal antibody with the CD47 binding domain of SIRP $\alpha$  on both heavy chains. It exerts excellent cancer killing effect by activating both macrophages and natural killer cells via blockade of CD47-SIRP $\alpha$  interaction and FcyR engagement. Here, we report the safety and efficacy results in patients (pts) with relapsed or refractory follicular lymphoma (R/R FL) from a phase II study (NCT05805943).

Methods: Eligible patients with FL Grade 1-3a received intravenous Amulirafusp alfa once a week of a 28-day treatment cycle with dose of 2.0 mg/kg until disease progression or intolerable toxicity. Safety was evaluated per the Common Terminology Criteria for Adverse Events version 5.0. Tumor assessments were performed by Lugano 2014. The primary endpoint was objective response rate (ORR). The secondary endpoints including disease control rate (DCR), progression free survival (PFS), and safety.

Results: As of Mar 14, 2024, 16 pts with FL were enrolled. The median age was 61 years old with 10 (62.5%) males. The median prior lines of therapy were 4. All 16 pts received previous anti-CD20 therapy. The most common treatment related adverse events (TRAEs) were lymphocyte (LYM) decreased (68.8%), platelet (PLT) decreased (50.0%), white blood cell (WBC) decreased (43.8%), anemia (43.8%) and absolute neutrophil count (ANC) decreased (31.3%). ≥ Grade 3 TRAEs occurred in 62.5% of pts. The most common ≥ grade 3 TRAEs were LYM decreased (50.0%), PLT decreased (18.8%), ANC decreased (18.8%) and pneumonia (18.8%). 18.8% of pts experienced serious TRAEs, all was pneumonia, in which 2 pts were recovering and 1 pts recovered without sequelae. No adverse event led to drug reduction, discontinuation or death. Among 15 efficacy evaluable pts with R/R FL, the ORR and DCR assessed by investigator was 33.3% and 66.7%, respectively. With a median follow-up of 5.72 months, the PFS rate at 9 months was 58.3%.

Conclusions: Amulirafusp alfa (IMM0306) was well-tolerated and presented robust preliminary anti-tumor activity in pts with R/R FL. This phase II study is ongoing.

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## 840P

Orelabrutinib-based regimens in chronic lymphocytic leukemia with comorbidities: A real-world study

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Background: Targeted therapy with Bruton's tyrosine kinase inhibitors (BTKis) become the standard of care for chronic lymphocytic leukemia (CLL). Orelabrutinib (O) is a novel BTKi with high selectivity and a favorable safety profile. Despite substantial benefits in CLL with O, real-world data remains scarce. This study aimed to evaluate the efficacy of O-based regimens for CLL with comorbidities in a real-world setting.

Methods: Data were retrospectively reviewed for 15 pts with CLL who underwent O-based regimens from Jun. 10, 2022, to Sep. 10, 2023. The outcome was the hematologic response (HR) rate, defined as the proportion of pts with abnormal baseline hematologic parameters who had a hemoglobin (Hb) response, platelet (Plt) response, or lymphocyte (Lym) response (Hb/Plt/Lym count return to or reduce >50% from baseline).

Results: Baseline characteristics of the pts are presented in the table. The median duration of O therapy was 10.7 months (interquartile range [IQR], 8.6-14.9). At the data cut-off (Apr. 26, 2024; median follow-up, 12.7 months), 14 (93.3%) pts achieved an HR. The remaining 1 pt that did not reach HR was a third-line treatment pt with HBV infection, and there was some recovery of hematologic indexes. Regarding different O-based regimens, HR was achieved in 100% (8/8) of pts receiving O monotherapy and 85.7% (6/7) receiving O + chemotherapy. No serious adverse events occurred in the pts with comorbidities.

Table: 840P Baseline characteristics	
Characteristics	All (n=15)
Sex (n, %) Male Female Median age, years (IQR) Rai stage (n, %)	11 (73.3) 4 (26.7) 62.0 (59.0-66.5)
           /  V	4 (26.7) 6 (40.0) 5 (33.3)
Binet stage (n, %) A B C	2 (13.3) 7 (46.7) 6 (40.0)
Previous number of prior therapies (n, %) 0 1 2	13 (86.7) 1 (6.7) 1 (6.7)
CLL-IPI score (n, %) 2-3 4-6 Unknown	1 (6.7) 2 (13.3) 12 (80.0)
IGHV status (n, %) Mutated Unmutated Unknown Comorbidity (n, %) Respiratory infection HBV/EBV infection Cardiovascular/cerebrovascular disease Endocrine disease Unknown	4 (26.7) 2 (13.3) 9 (60.0) 12 (80.0) 3 (20.0) 4 (26.7) 5 (33.3) 4 (26.7) 3 (20.0)
Regimens (n, %) O O + chemotherapy	8 (53.3%) 7 (46.7%)

Conclusions: O-based regimens demonstrated encouraging HR and were well tolerated in CLL with comorbidities, providing valuable insights for clinical management.