ASSESSMENT OF OVERALL SURVIVAL AND SAFETY IN NEWLY APPROVED ONCOHEMATOLOGIC DRUGS

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BACKGROUND

To be included on the WHO Model List of Essential Medicines, **cancer drugs should increase OS by at least 4-6 months**.

AIM AND OBJECTIVES

To evaluate OS benefit and safety of oncohematological drugs approved by the EMA from 2017 to 2020.

MATERIALS AND METHODS

Retrospective observational study

EMA aprobations 2017-2020

First indication of new oncohematological drugs

Source of information: European Public Assessment Reports

Variables collected: Primary endpoint, HR of OS with confidence intervals, OS benefit in months and total grade 3 or 4 adverse events

Descriptive statistics and Student's t-test to compare ADE.

RESULTS

49 indications of new drugs

41 (83.7%) Surrogate Endpoint

8 (16.3%) Overall Survival

4 indications (8.2%) with OS benefit as a secondary endpoint

OS BENEFIT

Median HR 0.71 [IQI 0.59-0.77]

Median Interval Width 0.36 [IQI 0.29-0.42]

- Response Rate (20)
- Progresión free survival (15)
- Disease free survival (2)
- Metastasis free survival (2)
- Invasive disease free survival (1)
- Pharmacokinetic (1)

GLOBAL OVERALL SURVIVAL BENEFIT 12 indications (24,5%)

- ▪8 as primary and 4 as secondary endpoint
- ▪Median not reached in 2 (16.7%)
- ▪ Median of 4.1 months [IQI 3.6-16.7]
- ▪6 (50%) equal to or exceeding 4 months.

SAFETY

Mean of serious AE

NEW DRUG	CONTROL
63.6%	52.2%

p< 0.05

CONCLUSIONS

- ❑ OS was the primary endpoint in 1 in 6 approved indications. While HR values were acceptable, considerable interval widths were noted.
- ❑ Approximately one-quarter of indications demonstrated OS benefit and six approved indications met the lower limit for inclusion in the WHO Model List of Essential Medicines.
- ❑ Despite modest OS outcomes, statistically significant increases in AE were observed.

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ABSTRACTS