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Monitoring evidence on overall survival benefits of anticancer drugs approved by the EMA

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Background and project aim

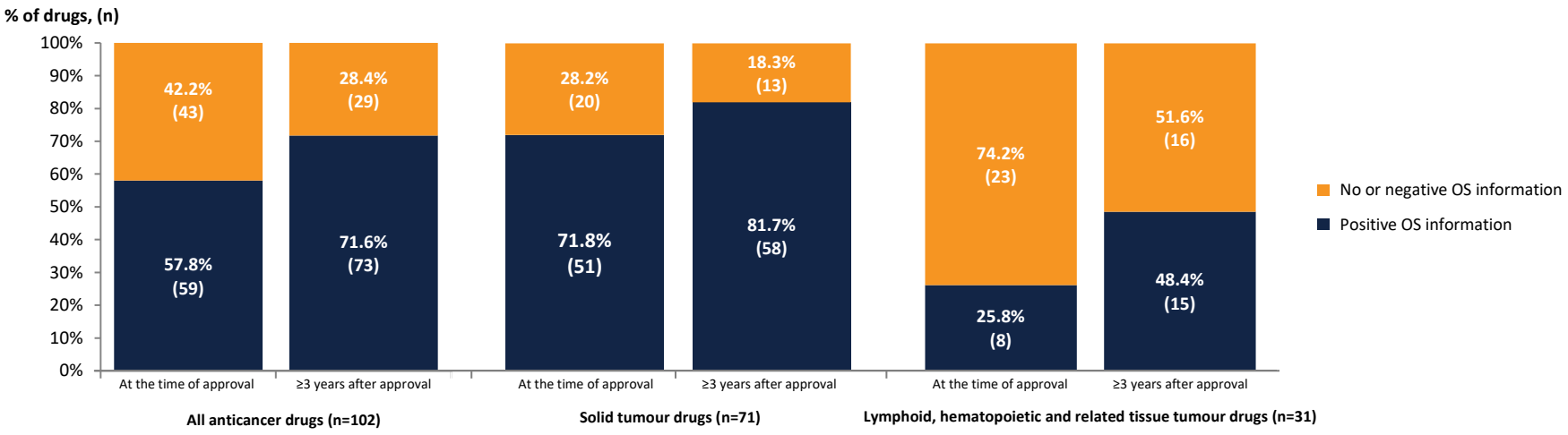
The introduction of fast-track licensing strategies increases the approval of anti-cancer drugs with ambiguous benefit-risk profiles [1]. Thus, in many instances there is lacking evidence about overall survival (OS) at the time of marketing authorisation [2-4]. Our objective was to monitor and characterise therapies with ambiguous benefit-risk profiles and identify any post-approval updates on median OS after at least three years of approval by the European Medicines Agency (EMA).

Methods

In our cross-sectional analysis, we included all originator anti-cancer drugs with initially ambiguous benefit-risk profiles that received marketing authorisation by the EMA between Jan 1, 2009 and May 31, 2015. Our monitoring timeframe for the identification of OS updates was at least three years after EMA-approval. To identify study updates, the following three sources were included: clinicaltrials.gov, EPARs, and PubMed, whereby the terms for the systematic literature search were "(name of the active substance) AND (NCT number OR trial name)" with no further restrictions.

Results

In total, we identified 102 eligible approval studies. Out of these, a negative difference in median OS or no information was available in 43 (42.2%) instances. During monitoring, 11 updates with accessible information on median OS could be identified. Including monitoring results, there are still 32 remaining therapies (31.4%) where no or negative information (n=27 [26.5%] and n=5 [4.9%], respectively) regarding median OS is present at least three years after EMA approval.



Conclusion

One-third of oncology drugs with ambiguous benefit-risk profiles fail to demonstrate a survival benefit even after several years of marketing authorisation. Systematic and transparent post-approval monitoring mechanisms will be of high relevance to assure a clinically relevant patient benefit, since the trend towards faster access to medicine with uncertain benefit is increasing rather than declining.

References

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