FORUM 1

How Good Are Our Medicines? - An operational agenda for EU & national policy-makers

Wednesday, 3 October 2018 | 14.45-17.15 | Room 2

Assessing the Quality of Innovation

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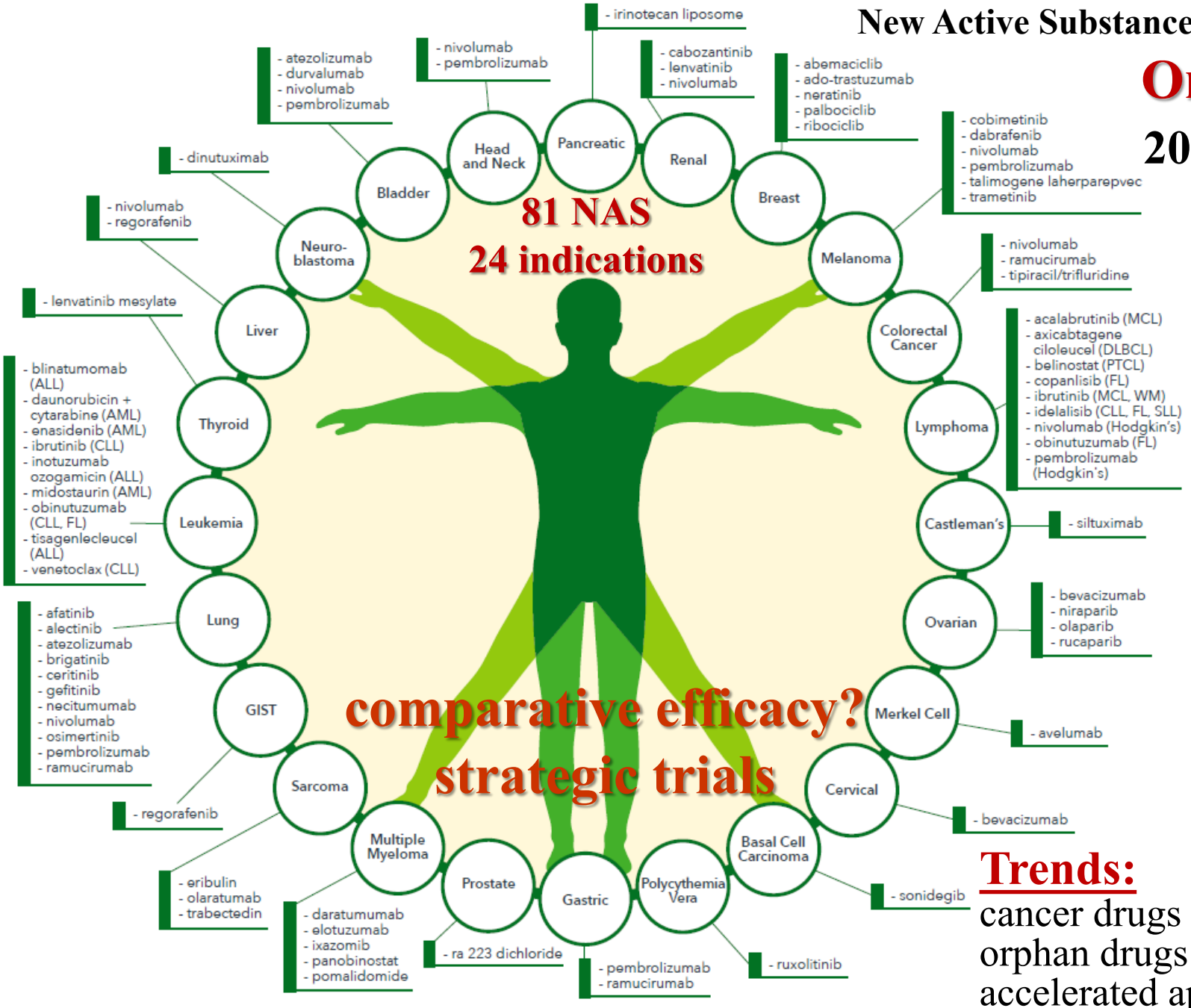
New Active Substance Approvals:

Oncology

2013-2017



Source: IQVIA, ARK R&D Intelligence, Apr 2018; IQVIA Institute, Apr 2018

Trends:

cancer drugs ▲
orphan drugs ▲
accelerated approvals ▲
first-in-class ▼

Urgent problems and possible solutions

- Research agendas (R & D of new drugs) driven by health care requirements and not by anticipated profitability
  (more financial commitments from governments)
- Inexorable growth of the orphan drug (OD) market and misuse of the orphan legislation (► threshold values for rare disease/definition of OD designation/„significant benefit“/(economic) incentives granted should be discussed and amended
- Concept of accelerated approvals ► limited clinical evidence at marketing authorization (benefit-risk/(cost-)effectiveness?)
- Obligation to perform confirmatory RCTs after approval and stringent monitoring of performance/completion/publication (sanctions?)
- More transparency as to communication between EMA, HCP, patients, pharmaceutical industry (e.g., scientific advice/early dialogue)