



MEDExpansion

Medical Intelligence
at the core of innovation

Considerations about immunotherapeutic medicines in oncology

Alain Rinaldi MD, Bratislava June 1st, 2023



Alain Rinaldi

- **Clinician (F, 84 - 91)**
 - Pediatrician, medical oncologist with hospital practice
- **Pharma (F, EU, 91 - 2014)**
 - Medical, medical affairs
 - Sanofi-Aventis, Servier, AstraZeneca
 - Alexion (2006 – 14)
 - ❖ Medical director France, then CH, Central & Eastern Europe countries
 - ❖ Launches of eculizumab (Soliris®) in FR, CH, IT, SK, CZ, PL, RO, HU, LT
- **Medexpansion (CH, 2014 - today)**
 - Collaborations with startups in oncology in the CMO role to help transition preclinical-to-clinical
- ***Member of CEEHPN since 2014***

Importance of facilitating access to IT drugs for better patient benefits



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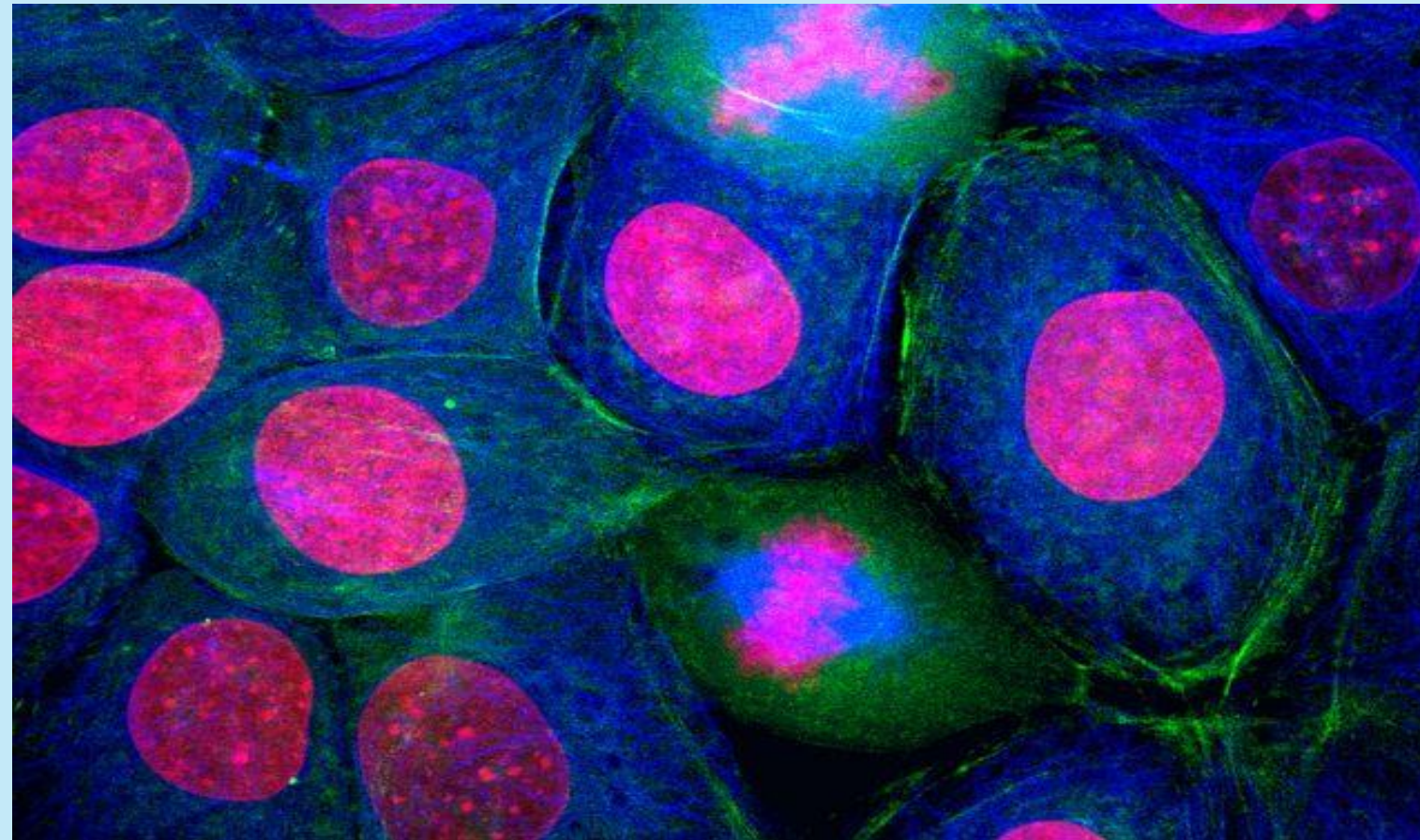
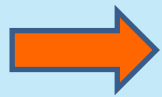
	1992 - 95	2023
Metastatic melanoma <i>5-year survival</i>	14%	40%
Metastatic lung cancer <i>Death rate</i>	60%	32%



Anti-cancer therapies: the historical situation before new therapies

Tumour

**One-fit-all
Chemotherapy**



Cancer cell death

Genomics/NGS*, launching pad for personalized medicine 2008 - 2023

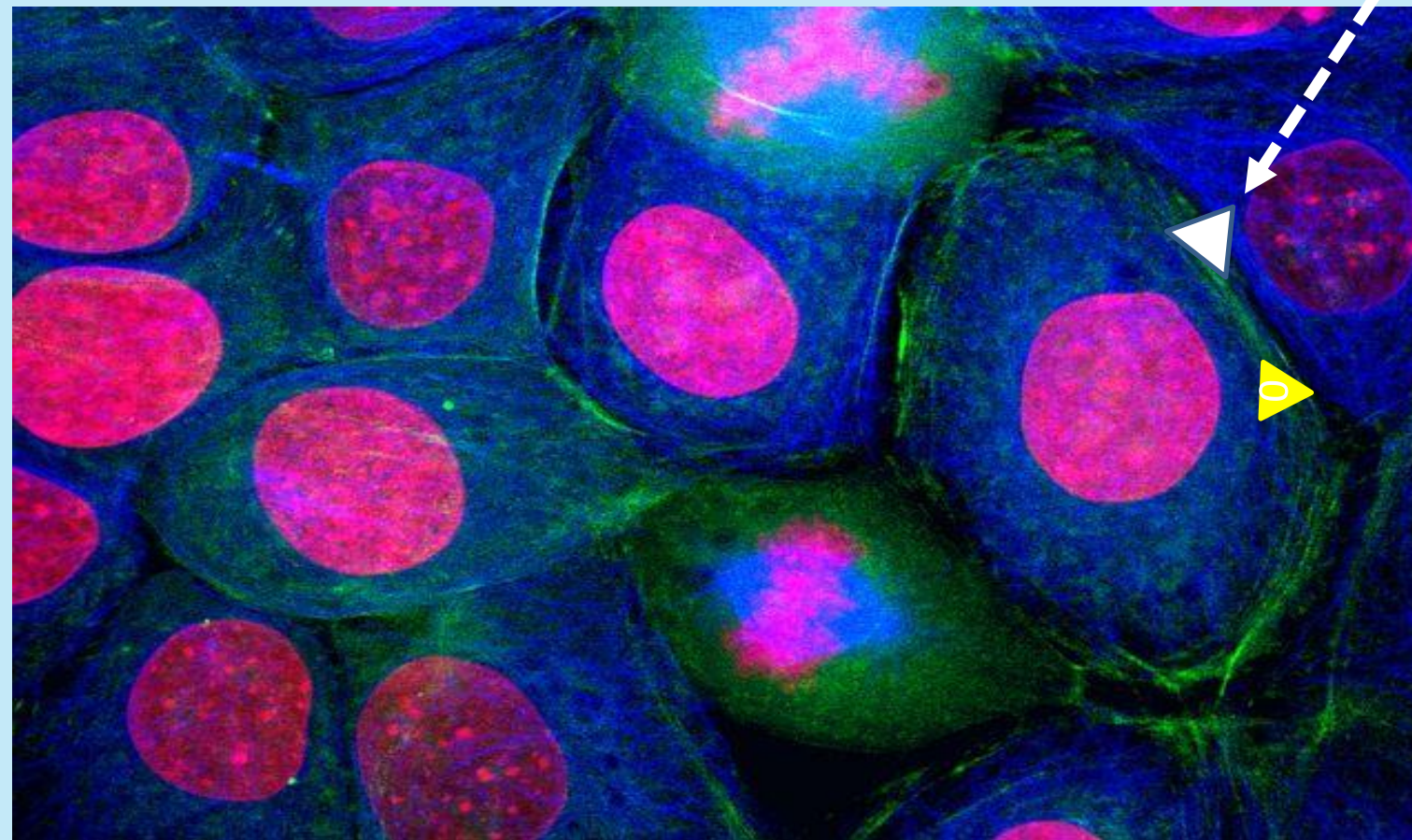
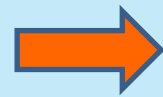


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Tumour

**Biomarkers, specific to the patient's
tumour, predictive of treatment efficacy**

Chemotherapy



Cancer cell death

*Next generation
sequencing of the DNA

Genomics, targeted therapies, immunotherapies and personalized medicine

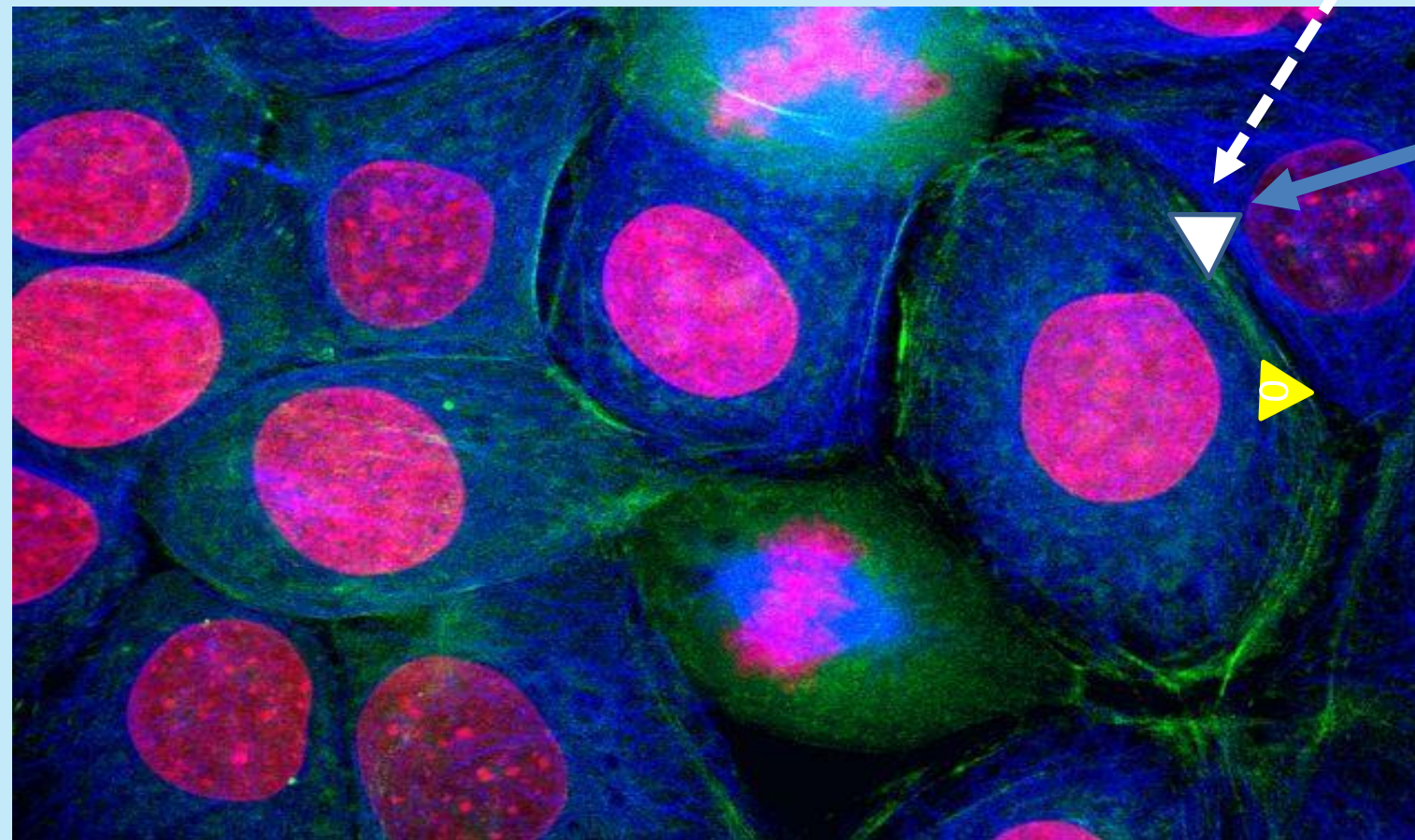


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Tumour

Biomarkers, specific to the patient's tumour, predictive of treatment efficacy

Targeted therapies and mAbs

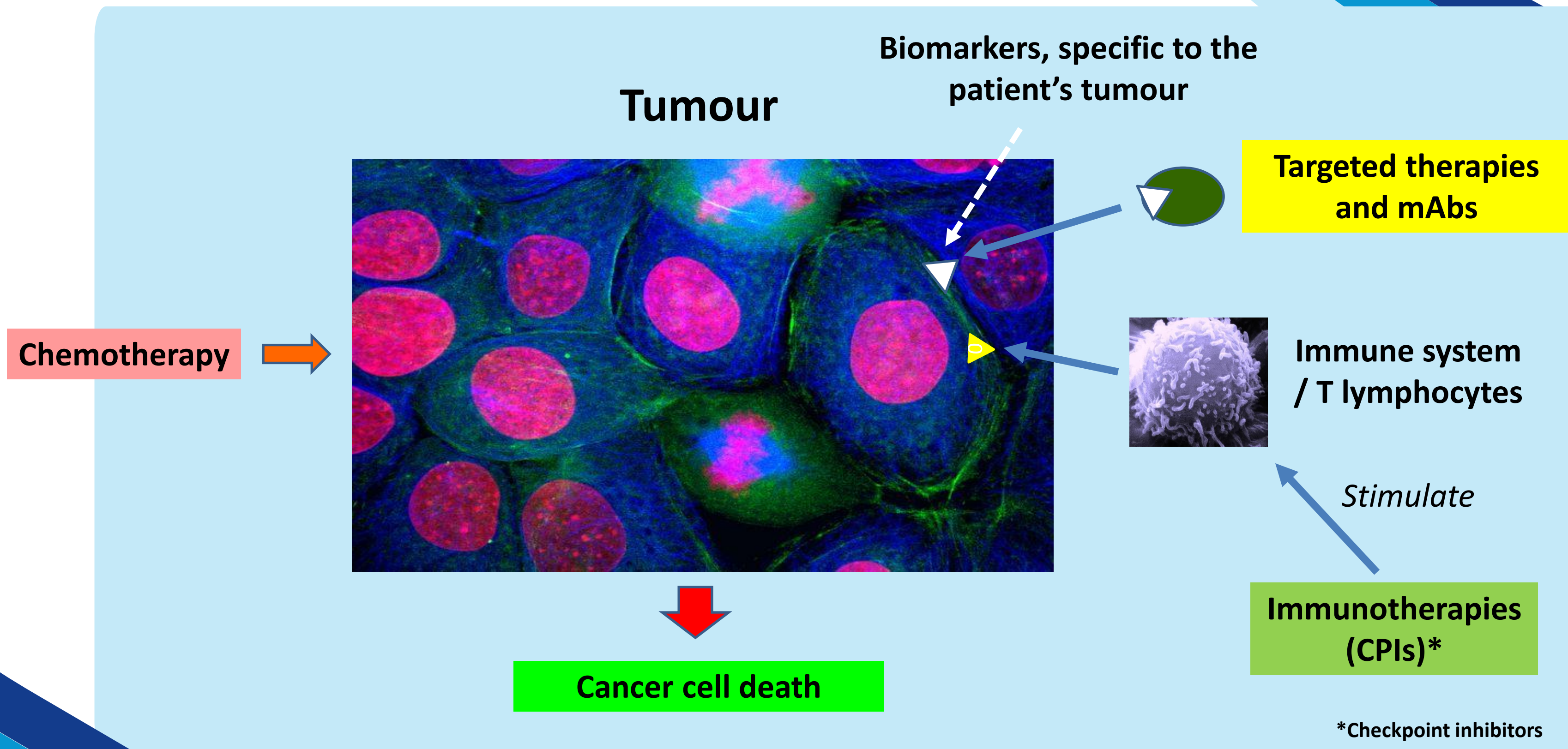


Chemotherapy →

↓
Cancer cell death



Genomics, targeted therapies, immunotherapies and personalized medicine



*Checkpoint inhibitors



New therapies have offered tremendous progress

- **Gain of efficacy**
 - Prolonged survival
 - Longer duration of response to treatment
 - In many cases, treatment cures patients with cancer or cancer becomes a chronic disease (prostate, breast ...)
- **Gain of safety**
 - Better tolerance (less hair loss, less vomiting ...)
- **Greater acceptability**
 - Frequent oral administration (targeted therapies)

Limitations to access : high costs and affordability issues (order of magnitude)

- **Almost all new therapies, targeted/immunotherapies, are expensive**
 - Eculizumab (orphan diseases): 470'000 € / year
 - Imatinib (lymphomas): 28'000 € / year
 - Sofosbuvir (hepatitis C): \$ 25'000 / one time 3 months
 - CAR T cell therapies (gene therapies, leukemias ...): M\$ 0,5 – 1 / one inj.
 - Pembrolizumab (CPI, oncology): 90'000 € / year (Keytruda® 2022 sales \$ 20.94 billions)

→ Escalation of healthcare budgets

- Increasing numbers of approved diseases and of eligible patients

• ... and the 2023 winners are ...

- Zynteglo®, Hemgenix® (gene therapies, resp. thalassemia, hemophilia B): resp. M\$ 2,8 and 3,5 / one inj.



... but precision medicine has imprecisions

- **Targeted therapies**

- Transient efficacy due to development of cancer resistances (mutations)
 - ➔ More expensive new generations of drugs to overcome resistances
 - ❖ G1 anti-EGFR gefitinib 9'500 €, G3 osimertinib 72'000 € (France)
 - ➔ Strategies for escalation?

- **Immunotherapies (Keytruda® ...)**

- Only 25 – 45% of eligible patients (predictive biomarker PD-L1) respond to treatment
 - ➔ Costly ineffective treatments sources of toxicities
 - ❖ 6-month treatment with pembrolizumab 45'000 €
 - ➔ Better patient selection?



Possible takeaways from CH/FR/US for new healthcare policies

- **Expert committees to revisit criteria for optimal patient profiles**
 - CPIs: improving predictive biomarkers
 - Targeted therapies: evidence-based recommendations for G1-Gx escalation
 - Restricting prescription to patients with best predictive benefits



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 - Price negotiation
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 - Cost-sharing mechanisms



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Thank you !



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