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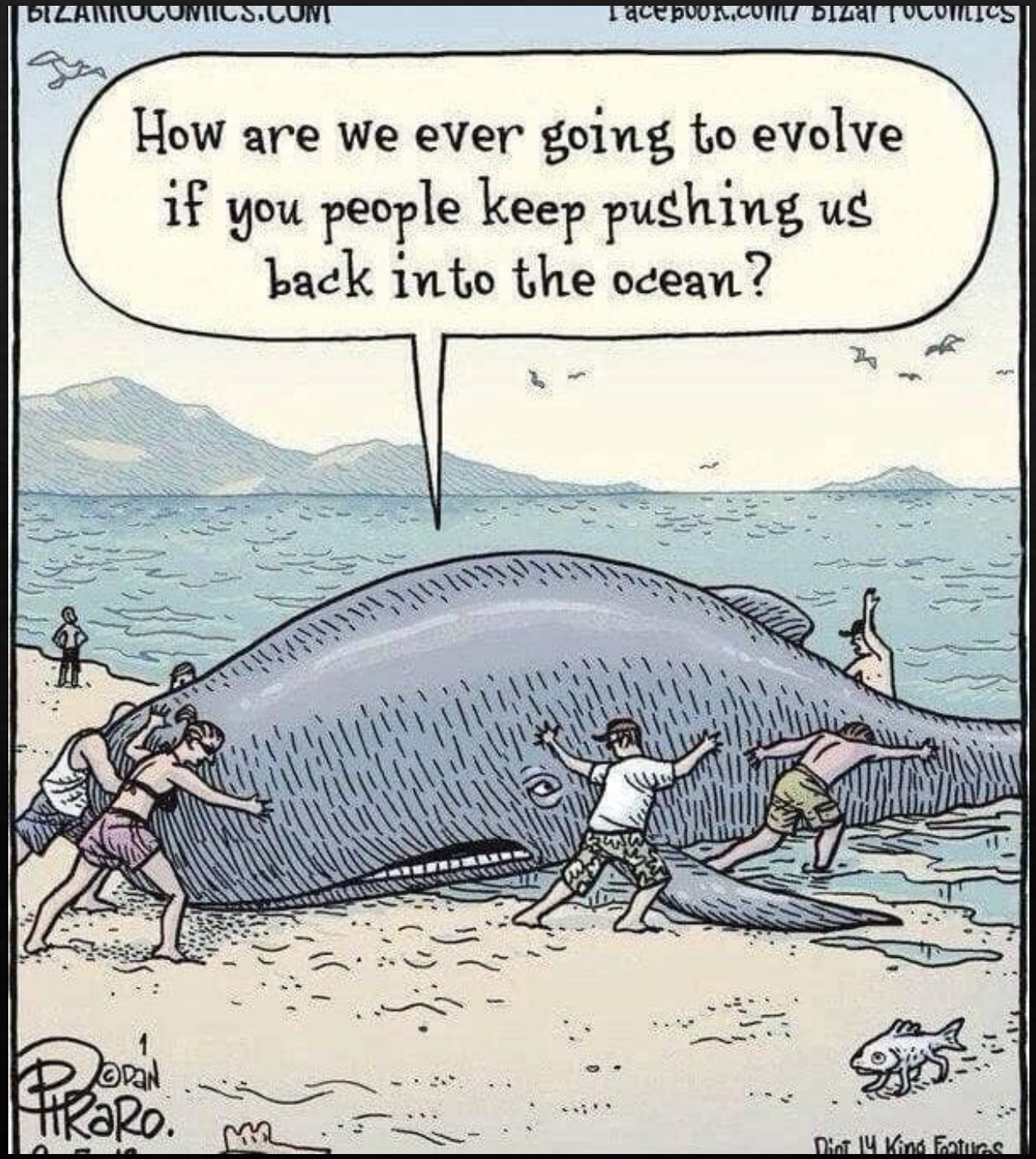
Capmatinib plus osimertinib versus platinum-pemetrexed doublet chemotherapy as second-line therapy in patients with stage IIIb/IIIc or IV *EGFR*-mutant, T790Mnegative NSCLC harboring *MET* amplification.

Dr Sunit Lokwani

Consultant Medical Oncologist,

Kokilaben Dhirubhai Ambani Hospital, indore


How are we ever going to evolve if you people keep pushing us back into the ocean?
Dan Piraro.


CELLFIE TIME!


BC-2300

TPS9153 **Poster Session**

Capmatinib plus osimertinib versus platinum-pemetrexed doublet chemotherapy as second-line therapy in patients with stage IIIb/IIIc or IV *EGFR*-mutant, T790M-negative NSCLC harboring *MET* amplification.

Yi-Long Wu, Ji-Youn Han, Terufumi Kato, Fabrice Barlesi, Edward B. Garon, Federico Cappuzzo, Yuji Shibata, Nathalie Smith, Sadhvi Khanna, Riccardo Belli, Alejandro Javier Yovine, Daniel S.W. Tan; Department of Guangdong Lung Cancer Institute, Guangdong Provincial People's Hospital and Guangdong Academy of Medical Sciences, Guangzhou, China; The Center for Lung Cancer, National Cancer Center, Goyang, South Korea; Department of Thoracic Oncology, Kanagawa Cancer Center, Yokohama, Japan; Cancer Medicine Department, Gustave Roussy, Villejuif, France; Ronald Reagan UCLA Medical Center, Santa Monica, CA; UOC Oncologia Medica, Istituto Nazionale Tumori "Regina Elena", Roma, Italy; Department of Thoracic Oncology, National Cancer Center Hospital East, Kashiwa, Japan; Novartis Pharma AG, Basel, NJ, Switzerland; Novartis Pharma S.A.S, Paris, France; Novartis Pharma AG, Basel, Switzerland; National Cancer Centre Singapore, Singapore, CA, Singapore

Premise / Background

- *MET* amplification can arise as a bypass resistance mechanism to EGFR tyrosine kinase inhibitors (TKIs).
- ~5-26% of EGFR TKI resistant *EGFR*-mutant non-small cell lung cancer (NSCLC)
- These patients (pts) have limited treatment options, particularly in the *EGFR* T790M negative (T790M−) setting.
- Capmatinib, a MET inhibitor, is approved in about 10 countries for the treatment of metastatic *MET* exon 14 skipping NSCLC.

- GEOMETRY-E (NCT04816214)

is a randomized, controlled, open-label, multicenter, phase 3 study evaluating the efficacy and safety of capmatinib + osimertinib vs platinum-pemetrexed doublet chemotherapy as second line treatment for advanced NSCLC.

Methods

- Ongoing study.
- Began in September 2021.

Pts with

- Stage IIIB/IIIC or IV *EGFR*-mutant, T790M−, *MET*-amplified NSCLC,
- progressed on either 1st/2nd generation EGFR TKIs, osimertinib or other 3rd generation EGFR TKIs.

- Pts with neurologically unstable, symptomatic CNS metastases or those requiring increasing doses of steroids ≤2 weeks prior to study entry to manage CNS symptoms are ineligible.

- 2-part study
- Part 1 (initial run-in,~10 pts) will confirm the recommended dose for the randomized Part 2 and evaluate the safety and tolerability of capmatinib + osimertinib.

- Part 1 - pts will receive oral capmatinib 400 mg twice daily + osimertinib 80 mg once daily in 21-day cycles.

- Part 2 – will evaluate the efficacy and safety of capmatinib + osimertinib vs platinum (cisplatin/carboplatin)-pemetrexed.
- Part 2 ~225 pts, 2:1 randomization,
- stratified by the presence of brain metastases (yes/no) &
- prior treatment with 3rd generation EGFR TKIs (yes/no).

- Part 1 - Primary endpoint is the incidence of dose limiting toxicities during the first 21 days of treatment.
- Secondary endpoints include safety; tolerability; pharmacokinetics (PK); investigator-assessed overall response rate (ORR), duration of response (DOR), time to response (TTR), disease control rate (DCR) and progression-free survival (PFS) per the Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST 1.1)

- Part 2 - Primary endpoint is blinded independent review committee (BIRC)-assessed PFS per RECIST 1.1.
- Secondary endpoints are ORR by BIRC per RECIST 1.1 and overall intracranial response rate (OiRR) by BIRC per Response Assessment in Neuro-Oncology Brain Metastases (RANO-BM)

- Other secondary endpoints include DOR, TTR and DCR by BIRC; investigator-assessed PFS after next line of treatment; PK; safety; overall survival; patient-reported outcomes; intracranial DCR, duration of & time to intracranial response by BIRC per RANO-BM.

- The results are yet to be published.

- Thank you for patient listening....

You make your life hard by always being in your head. Life is simple, get out of your head and get into the moment.

—s. mcnutt