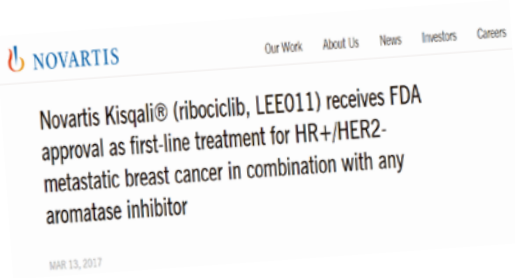
EU Competition Law in Sales and Distribution of Healthcare Products
19 May 2017 University of Basel-Law Faculty

Combination therapies with products from different producers

EU Competition Law analysis

Stefan Arnold


NOVARTIS

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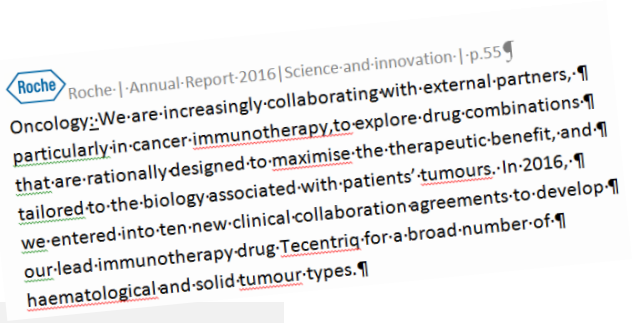
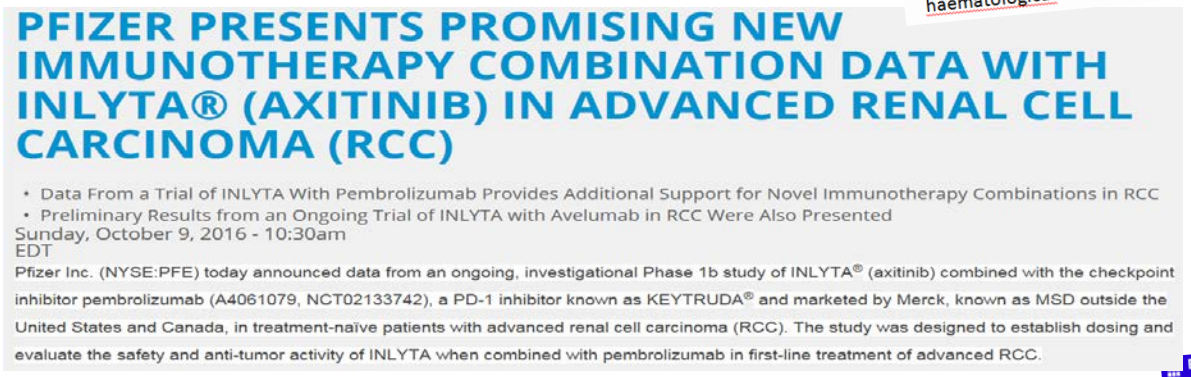
Novartis Kisqali® (ribociclib, LEE011) receives FDA approval as first-line treatment for HR+/HER2- metastatic breast cancer in combination with any aromatase inhibitor

MAR 13, 2017


Roche · | · Annual Report 2016 | Science and innovation · | · p.55

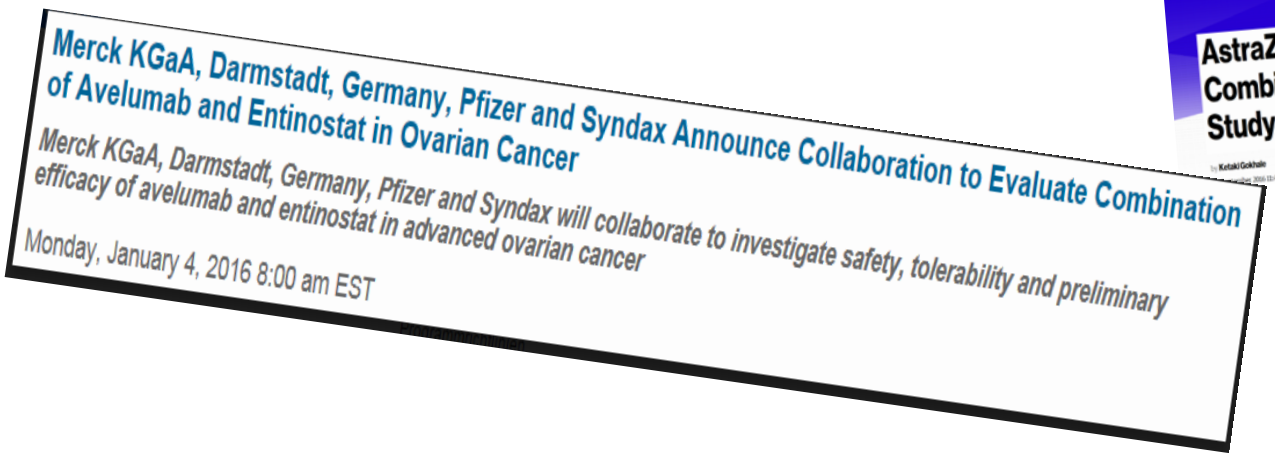
Oncology: We are increasingly collaborating with external partners, particularly in cancer immunotherapy, to explore drug combinations that are rationally designed to maximise the therapeutic benefit, and tailored to the biology associated with patients' tumours. In 2016, we entered into ten new clinical collaboration agreements to develop our lead immunotherapy drug Tecentriq for a broad number of haematological and solid tumour types.


PFIZER PRESENTS PROMISING NEW IMMUNOTHERAPY COMBINATION DATA WITH INLYTA® (AXITINIB) IN ADVANCED RENAL CELL CARCINOMA (RCC)

- Data From a Trial of INLYTA With Pembrolizumab Provides Additional Support for Novel Immunotherapy Combinations in RCC
- Preliminary Results from an Ongoing Trial of INLYTA with Avelumab in RCC Were Also Presented

Sunday, October 9, 2016 - 10:30am EDT

Pfizer Inc. (NYSE:PFE) today announced data from an ongoing, investigational Phase 1b study of INLYTA® (axitinib) combined with the checkpoint inhibitor pembrolizumab (A4061079, NCT02133742), a PD-1 inhibitor known as KEYTRUDA® and marketed by Merck, known as MSD outside the United States and Canada, in treatment-naïve patients with advanced renal cell carcinoma (RCC). The study was designed to establish dosing and evaluate the safety and anti-tumor activity of INLYTA when combined with pembrolizumab in first-line treatment of advanced RCC.


Merck KGaA, Darmstadt, Germany, Pfizer and Syndax Announce Collaboration to Evaluate Combination of Avelumab and Entinostat in Ovarian Cancer

Merck KGaA, Darmstadt, Germany, Pfizer and Syndax will collaborate to investigate safety, tolerability and preliminary efficacy of avelumab and entinostat in advanced ovarian cancer

Monday, January 4, 2016 8:00 am EST


Bloomberg · Markets · Tech · Pursuits · Politics · Opinion · Businessweek

AstraZeneca Diabetes Drug Combination Shows Promise in Study

by Ketaki Gokhale

On the way to the market

- Increase in developments of combination treatments with products from
  - one company
  - two or more companies
- Co-operation
  - necessary if other company's product not available on the market
  - beneficial if other company's product supplied at interesting terms

On the way to the market

Base Case:

- Company A wants to develop its product A for a combination therapy with product B of company B in indication 1
- Agreement between company A and B
  - B supplies drug B to be used in clinical study performed by A with products A and B for indication 1
  - A grants B the right to use the study results

On the way to the market

Base case (continued)

- Product B belongs to a distinct class of products
  - Product C of company C and product D of company D belong to the same class
  - Product A belongs to a different class
  - All three products B, C and D equally qualify for use in combination with product A for indication 1

On the way to the market

Variations to the base case

- Product A is the only product that might be used in combination with products B, C and D for indication 1
- Product A has a significant market share in indication 2
- Product B has a significant market share in indication 3
- Product B is also registered for indication 2

On the way to the market

Base case plus

- Additional scenario 1
  - Company A agrees with regard to indication 1 to develop product A only for the combination with product B
- Additional scenario 2
  - Company A agrees to only register the combination of product A and B and not product A with the entire class of products to which product B belongs
- Additional scenario 3
  - Company A agrees to use the results of the trial only for the registration of the combination of product A and B

Price hits as a result of success

- Base case:
  - Agreement between company A and B
    - B supplies drug B to be used in clinical study to be performed by A with products A and B for indication 1
    - A grants B the right to use the study results
- Result of a successful registration of the combination indication for product A:
  - Constraints of health care budgets
  - Additional indications
    - development risk, costs
    - reduction of reimbursment price and financial hit for developing company in some countries
  - Potential windfall profit for other company

Price hits as a result of success

- Can companies A and B discuss and agree on a solution that takes care of the consequences of company A having a lower price for product A after registration of the combination treatment A and B for product A?

- Thank you for your attention
- Questions?

Art. 101 TFEU

Article 101 TFEU
(ex Article 81 TEC)

1. The following shall be prohibited as incompatible with the internal market: all agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the internal market, and in particular those which:

(a) directly or indirectly fix purchase or selling prices or any other trading conditions;

(b) limit or control production, markets, technical development, or investment;

(c) share markets or sources of supply;

(d) apply dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;

(e) make the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.

2. Any agreements or decisions prohibited pursuant to this Article shall be automatically void.

3. The provisions of paragraph 1 may, however, be declared inapplicable in the case of:

- any agreement or category of agreements between undertakings,
- any decision or category of decisions by associations of undertakings,
- any concerted practice or category of concerted practices,

which contributes to improving the production or distribution of goods or to promoting technical or economic progress, while allowing consumers a fair share of the resulting benefit, and which does not:

(a) impose on the undertakings concerned restrictions which are not indispensable to the attainment of these objectives;

(b) afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products in question.

Art. 102 TFEU

Article 102 TFEU

(ex Article 82 TEC)

Any abuse by one or more undertakings of a dominant position within the internal market or in a substantial part of it shall be prohibited as incompatible with the internal market in so far as it may affect trade between Member States.

Such abuse may, in particular, consist in:

(a) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions;

(b) limiting production, markets or technical development to the prejudice of consumers;

(c) applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;

(d) making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.