

Clinical trials of Phosphoinositide 3-kinase inhibitor for advanced breast cancer (metastatic) in HR+ HER2-

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1 dual PI3K/mTOR inhibitor

| Trial | Treatments | Patients | Trials design and methods |
|--|---|---|---------------------------|
| GDC0941/GDC0980 vs fulvestrant alone | | | |
| NCT01437566 <i>ongoing</i> [NCT01437566] n=NA follow-up: | GDC-0941 or GDC-0980 + Fulvestrant versus palcebo + Fulvestrant | Advanced or Metastatic Breast Cancer in Patients Resistant to Aromatase Inhibitor Therapy | |

References

NCT01437566, :

2 Pan-PI3 K inhibitor

| Trial | Treatments | Patients | Trials design and methods |
|--|---|--|---------------------------|
| BKM120 + fulvestrant vs fulvestrant alone | | | |
| BELLE-2 <i>ongoing</i> [NCT01610284] n=1149 follow-up: | BKM120 and fulvestrant versus Placebo and fulvestrant | patients with hormone receptor-positive, HER2-negative locally advanced or metastatic breast cancer refractory to aromatase inhibito | double-blind |
| BELLE-3 <i>ongoing</i> [NCT01633060] n=420 follow-up: | BKM120 and fulvestrant versus Placebo and fulvestrant | patients with HR+, HER2-, AI treated locally advanced or metastatic breast cancer who progressed on or after mTor inhibitor based treatment | double-blind |
| BKM120 + paclitaxel vs paclitaxel | | | |
| BELLE-4 <i>ongoing</i> [NCT01572727] n=416 follow-up: | BKM120 and paclitaxel versus Placebo and paclitaxel | Patients With HER2 Negative Inoperable Locally Advanced or Metastatic Breast Cancer, With or Without PI3K Pathway Activation | double-blind |

References

BELLE-2, :

BELLE-3, :

BELLE-4, :

3 Pan-PI3K inhibitor/dual PI3K/mTOR inhibitor

| Trial | Treatments | Patients | Trials design and methods |
|---|--|---|---------------------------|
| XL147 (SAR245408) + letrozole vs XL765 + letrozole | | | |
| NCT01082068 <i>ongoing</i> [NCT01082068] n=72 follow-up: | XL147 (SAR245408) + letrozole versus XL765 + letrozole | Subjects With Hormone Receptor-Positive and HER2-Negative Breast Cancer Refractory to a Nonsteroidal Aromatase Inhibitor | |

References

NCT01082068, :

4 PI3K-alpha inhibitor

| Trial | Treatments | Patients | Trials design and methods |
|--|---|--|---------------------------|
| BYL719 + TAM + Gos vs BKM120 + TAM + Gos | | | |
| B-YOND <i>ongoing</i> [NCT02058381] n=40 follow-up: | alpelisib (BYL719) plus Tamoxifen and Goserelin versus buparlisib (BKM120) plus Tamoxifen and Goserelin | Premenopausal Patients With Hormone Receptor-positive/HER2-negative Locally Advanced or Metastatic Breast Cancer | |

References

B-YOND, :

5 About TrialResults-center.org

TrialResults-center is an innovative knowledge database that collects the results of RCTs and provides dynamic interactive systematic reviews and meta-analysis in the field of all major heart and vessels diseases.

The TrialResults-center database provides a unique view of the treatment efficacy based on all data provided directly from clinical trial results, offering a valuable alternative to personal bibliographic search, published meta-analysis, etc. Furthermore, it would allow comparing easily the various concurrent therapeutic for the same clinical condition.

Rigorous meta-analysis method is used to populate TrialResults-center: widespread search of published and non published trials, study selection using pre-specified criteria, data extraction using standard form.

TrialResults-center is continually updated on a weekly basis. We continually search all new results (whatever their publication channel) and these news results are immediately added to the database with a maximum of 1 week.

TrialResults-center is non-profit and self-funded.