

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

TrialResults-center www.trialresultscenter.org

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 placebo + 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.