

Clinical trials of Phosphoinositide 3-kinase inhibitor for advanced breast cancer (metastatic) in all type of patients

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1 Pan-PI3 K inhibitor

Trial	Treatments	Patients	Trials design and methods
alpelisib + fulvestrant vs fulvestrant alone			
SOLAR-1 <i>ongoing</i> [NCT02437318] n=NA follow-up:	Alpelisib (300 mg; oral; once daily) in combination with fulvestrant (500 mg; intramuscular injection on Day 1 and Day 15 of Cycle 1, and then Day 1 of each subsequent 28-day cycle)) versus fulvestrant (500 mg; intramuscular injection on Day 1 and Day 15 of Cycle 1, and then Day 1 of each subsequent 28-day cycle	Men and Postmenopausal Women With Advanced Breast Cancer Which Progressed on or After Aromatase Inhibitor Treatment	double-blind
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

SOLAR-1, 0:

BELLE-2, :

BELLE-3, :

BELLE-4, :

2 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, :

3 selective PI3K inhibitor

Trial	Treatments	Patients	Trials design and methods
taselisib + fulvestrant	vs fulvestrant alone		
SANDPIPER, 2018 [NCT02340221] n=340/176 follow-up:	taselisib (4 mg oral, qd) FULV (500 mg) versus palcebo FULV (500 mg)	postmenopausal women with estrogen receptor (ER)-positive, human epidermal growth factor receptor-2 (HER2)-negative, PIK3CA-mutant, unresectable, locally advanced or metastatic breast cancer after recurrence or progression during or after an aromatase inhibitor (AI) therapy	double-blind USA

References

SANDPIPER, 2018:

4 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.