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Breast Cancer: New targeted therapies transform treatment - KOL Insight

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Abstracts

The introduction of targeted therapies revolutionised the breast cancer market, widening clinical options and bringing improved survival rates and lower side effects for patients. Now the sector is set for further positive change and expansion as next generation products for HER2-positive disease come to market, and CDK4/6 and P13K inhibitors hold the prospect of new treatments for hormone receptor-positive and HER2-negative breast cancer patients – an area of huge unmet clinical need. Which are the companies and products that will change the commercial and clinical landscape over the next 5 years?

Among the main drivers of change in the breast cancer market.

Roche’s Kadcyla and Perjeta set to transform the treatment of HER2-positive breast cancer

Roche’s Kadcyla (ado-trastuzumab emtansine) and Perjeta (pertuzumab) are both viewed as significant steps forward in the treatment of breast cancer. When added to Herceptin (trastuzumab), Perjeta is the first drug to improve survival in the first-line setting since the availability of Herceptin in 1998. Kadcyla is the first antibody-drug conjugate for the treatment of breast cancer and improves overall survival by almost six months in the second-line setting. To Roche’s commercial benefit, both drugs are set to expand their indications and will likely dominate the market in both the early stages and first lines of treatment for metastatic disease.

No room for biosimilar Herceptin?

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Although the availability of biosimilar versions of Herceptin will likely expand in the near future, their prospects are not bright. Kadcyla and Perjeta look set to overtake Herceptin in the early stages and first-line treatment of metastatic HER2-positive breast cancer, thereby limiting the role of biosimilar trastuzumab. Furthermore, Roche's subcutaneous Herceptin offers more convenient administration than intravenous biosimilar versions. Clinical scepticism and defensive pricing will further limit the prospects for biosimilars in established markets.

New approaches will transform the treatment of hormone receptor-positive and HER2-negative breast cancer

While Novartis' Afinitor (everolimus) improves progression-free survival in patients with hormone receptor-positive, HER2-negative metastatic breast cancer, it is highly toxic. Interest is now focussed on promising late-stage pipeline candidates. Pfizer's palbociclib and Novartis' LEE011 are locked in a race to become the first-to-market CDK4/6 inhibitor. Both drugs are expected to improve survival when combined with an aromatase inhibitor in the first-line treatment of this patient segment and at a lower cost in terms of toxicity. The treatment of hormone receptor-positive, HER2-negative breast cancer will be transformed by the availability of these and PI3K inhibitors such as Pfizer's buparlisib (BKM120).

Unique insider clinical opinion

This new KOL Insight report Breast Cancer –new targeted therapies transform treatment provides everyone interested in this dynamic cancer sector with a complete understanding of the targeted products which are shaping the current landscape and the research which will change future treatment paradigms.

Every aspect of the report is informed by insights gained from thorough 60-minute interviews with 12 experienced key opinion leaders (KOLs) from across major markets to provide expert views on the current treatment landscape and how it will change in the future. KOLs are selected based on their clinical experience, authored scientific publications, involvement in clinical trials and with the Pharma industry, their participation in treatment guideline development, and their record of presenting at high-profile international conferences. They bring incisive, expert "real world" insights to this fast changing sector.

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This report tackles the pressing issues and questions in the breast cancer treatment market:

Which drug is the treatment of choice for each patient segment, line of therapy and unique patient characteristic, and what product attributes contribute to the preference, e.g. first-line treatment of HER2-positive, hormone receptor-positive and HER2-negative, or triple negative disease, and patients with brain metastases?

How is the product perceived by the medical community in terms of efficacy, tolerability, ease of administration, and other product attributes, and how does it compare with other treatment options?

Which recently completed or ongoing clinical trials have the greatest potential to impact prescribing trends and how will the results impact practice in the future, e.g. BOLERO-2, ALTTO, NeoALTTO, MARIANNE, APHINITY, KATHERINE, RESILIENCE, PALOMA-2, etc.?

What will a product need to show in order to become the treatment of choice in a specific patient segment and line of therapy and is it likely the product will meet these requirements?

How will the use of each product change in the future in terms of patient segments, line of therapy and preference, e.g. Roche’s Herceptin, Perjeta, and Kadclya, GlaxoSmithKline’s Tykerb, and Novartis’ Afinitor?

What will the pipeline products need to show in terms of efficacy and tolerability endpoints to effectively compete with current therapies, and what is the likelihood the pipeline products will achieve those endpoints?

Which pipeline products are the most promising and how will they impact current players in the market e.g. Pfizer’s CDK4/6 inhibitor palbociclib (PD 0332991), Novartis’ PI3K inhibitor buparlisib (BKM120) and AstraZeneca’s PARP inhibitor olaparib (AZD 2281)?

This report will allow you to:

Understand and evaluate the important drivers in targeted breast cancer

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treatments

Fully evaluate how the competitive landscape may change

Understand clinical opinions of current and futures products and how they will change treatment algorithms

Survey and appraise the late-stage product pipeline

KOL Insight Benefits

Understand and assess future breast cancer market developments

Analyse current and future treatment algorithms

Understand the strengths and weaknesses of currently available targeted therapies for breast cancer

Assess how prescribing trends will change with launch of new products

Identify promising late-stage pipeline products

Track KOL opinion continuously over the next 12 months

Selected Quotes from the Report

“There's more and more evidence showing that using combination HER2 blockade is the right thing to do. So, at the moment, I think it [Herceptin] will remain the backbone of the combination approach. If the patient relapsed on T-DM1 then you might go on to Herceptin plus pertuzamab or Herceptin plus pertuzamab plus another drug.” EU Key Opinion Leader

“There are issues that have not yet been well-defined for biosimilars. My decision to use a biosimilar will depend on the basis of approval. I need more transparency to be confident. Has it been used in the metastatic setting? Can it be used in the adjuvant setting? Will there be testing for cardiotoxicity? The answers to these questions should be clear. I don’t think there will be much use

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of biosimilar Herceptin because the criteria used by the European Medicines Agency (EMA) are very [different], so this drug [biosimilar Herceptin] is basically less tested. We don't trust the development." EU Key Opinion Leader

"T-DM1 [Kadcyla] is a tremendous step forward. It's as big an advance as Herceptin was when that was first developed. It's clearly very effective and it's also very well tolerated, so it's a win-win really for the patients. I've been amazed at both the responses and the low side-effect profile of treatment. So, I can see it probably sweeping the board in time." EU Key Opinion Leader

"Right now I am most excited and encouraged with the CDK 4/6 inhibitor palbociclib. It is an oral therapy; it is well tolerated; and it shows improvements in efficacy that are double to triple of what we have seen with hormonal therapy alone. So far, I am very excited about it and I think it is going to move quickly." US Key Opinion Leader

"PARP inhibitors could have a huge impact for a small subpopulation of patients that have a BRCA1 or BRCA2 mutation. Within those populations there is a good chance that they will indeed show better time to progression and survival." EU Key Opinion Leader

KOL Panel

KOLs from North America:

Dr. Carlos L. Arteaga MD is Associate Director for Clinical Research, Director, Breast Cancer Research Program, and Director, Center for Cancer Targeted Therapies at the Vanderbilt-Ingram Cancer Center (VICC), Vanderbilt University, Nashville, TN.

Dr. Kimberly L. Blackwell, MD is Professor of Medicine and Assistant Professor of Radiation Oncology at Duke University Medical Center, Durham, NC.

Dr. Adam M. Brufsky, MD, PhD, is Professor of Medicine at the University of Pittsburgh School of Medicine, Pittsburgh, PA.

Dr. Ana Maria Gonzalez-Angulo, MD, MSc, FACP, is Associate Professor, Department of Breast Medical Oncology and Chief, Section of Clinical Research

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and Drug Development, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center, Houston, TX.

Dr. Reshma Mahtani, DO is Assistant Professor of Clinical Medicine, Division of Hematology/Oncology, Miller School of Medicine, University of Miami, Miami, FL.

Dr. Charles Vogel, MD is Professor of Clinical Medicine, Division of Hematology/Oncology, Miller School of Medicine, University of Miami, Miami, FL.

KOLs from Europe:

Dr. Thomas Bachelot, MD, is Head of the Breast Cancer Unit and the Clinical Trial Unit at the Centre Leon Berard, Lyon, France.

Dr. Rob Coleman, MBBS, MD, FRCP, is Professor Department of Oncology, Weston Park Hospital, Sheffield, England, UK.

Dr. Alessandra Gennari, MD, PhD, is Medical Director, Medical Oncology Unit, Galliera Hospital, Genoa, Italy.

Dr. Adrian L. Harris, MD, DPhil is Professor of Medical Oncology at the University of Oxford and Director of the Cancer Research UK Medical Oncology Unit.

Professor Gunter von Minckwitz is Managing Director of the German Breast Group (GBG) Research Institute.

Dr. Rafael Trujillo is Medical Oncologist, Xanit International Hospital, Malaga, Spain.

Updated Continually

This report is continually updated in response to market developments stay in touch with the latest developments and thinking and maximise the value of this report

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The world of pharma is ever changing and executives must always be up-to-date with the latest developments that could affect their own products, position and research. That is why FirstWord's guarantee to keep Therapy Trends updated offers real commercial advantage. Consider the benefits:

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About

The goal of this FirstWord Therapy Trends report is to present a comprehensive qualitative review of targeted therapies in the breast cancer market with an emphasis on current and future treatment pathways. In order to achieve this goal, FirstWord analysts conduct detailed secondary research into current and late-stage pipeline therapies. This research focusses on the development of commercial and clinical profiles for each product, the identification of key clinical data, the isolation of key ongoing clinical trials, and the classification of the current treatment algorithm based on patient segment, line of therapy and patient characteristics.

Following this research, FirstWord conducts 60-minute telephone interviews with 12 key opinion leaders (KOLs) from across the major markets to provide expert views on the current treatment landscape and how it will change in the future. In order to ensure the quality of the interviews, the KOLs are carefully selected based on their clinical experience, authored scientific publications, involvement in clinical trials and with the Pharma industry, their participation in treatment guideline development, and their record of presenting at high-profile international conferences. Moderators with detailed knowledge of the market dynamics and a track record of obtaining valuable insights from the KOLs conduct the interviews with the following objectives:

- Which drug is the treatment of choice for each patient segment, line of therapy and unique patient characteristics, and what product attributes contribute to the preference e.g. first-line treatment of HER2-positive, hormone receptor-positive and HER2-negative, or triple negative disease, and patients with brain metastases?

- How is the product perceived by the medical community in terms of efficacy, tolerability, ease of administration and other product attributes, and how does it compare with other treatment options?

- Which recently completed or ongoing clinical trials have the greatest potential to impact prescribing trends and how will the results impact practice in the future e.g. BOLERO-2, ALTTO, NeoALTTO, MARIANNE, APHINITY, KATHERINE, RESILIENCE, PALOMA-2, etc.?

- What will a product need to show in order to become the treatment of choice in a specific patient segment and line of therapy and is it likely the product will meet these requirements?

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• How will the use of each product change in the future in terms of patient segments, line of therapy and preference e.g. Roche's Herceptin, Perjeta, and Kadclya, GlaxoSmithKline's Tykerb, and Novartis' Afinitor?

What will the pipeline products need to show in terms of efficacy and tolerability endpoints to effectively compete with current therapies, and what is the likelihood the pipeline products will achieve those endpoints?

• Which pipeline products are the most promising and how will they impact current players in the market e.g. Pfizer's CDK4/6 inhibitor palbociclib (PD 0332991), Novartis' PI3K inhibitor buparlisib (BKM120) and AstraZeneca's PARP inhibitor olaparib (AZD 2281)?

• How will the treatment landscape evolve in the future for each patient segment and line of therapy?

The insights obtained from both the primary and secondary research are organised by patient segment and begin with a concise overview, followed by more detailed insights focussed on each current and pipeline product. At the end of each patient segment, the current and future treatment algorithm for that segment are summarised, allowing rapid identification of key players and expected future developments.

KOLs from North America

Dr. Carlos L. Arteaga MD is Associate Director for Clinical Research, Director, Breast Cancer Research Program, and Director, Center for Cancer Targeted Therapies at the Vanderbilt-Ingram Cancer Center (VICC), Vanderbilt University, Nashville, TN. He is also Professor of Medicine and Cancer Biology. Dr. Arteaga authored over 250 publications in the areas of signaling by growth factor receptors and oncogenes in breast tumor cells, development of targeted therapies and biomarkers of drug action and resistance and investigator-initiated clinical trials in breast cancer. Since 2002, he has directed the NCI-funded Vanderbilt Breast Cancer SPORE where he co-leads several investigator-initiated clinical trials. He served as member of the Experimental Therapeutics-2 NIH Study Section (1998-2003), the NCI Board of Scientific Counselors (1999-2004), NCI Parent Subcommittee A for review of Cancer Centers (2004-2008), the Breast Core Committee of the Eastern Cooperative Oncology Group (ECOG), and the Board of Directors of the American Association for Cancer Research (2004-2007). As of 2012, he serves in the Scientific Advisory Board of the Komen Foundation. He has chaired the AACR Special Conference 'Advances in Breast Cancer Research' since

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2003 and has served as AACR co-chair of the annual San Antonio Breast Cancer Symposium since 2009. He is Deputy Editor of Clinical Cancer Research and member of the Editorial Board of Cancer Cell and six other peer-reviewed journals. He serves on the advisory boards of several academic cancer center-based Breast Cancer Programs and NCI-designated Cancer Centers. In 2013, he was voted by the AACR membership as President Elect of the American Association for Cancer Research.

Dr. Kimberly L. Blackwell, **MD** is Professor of Medicine and Assistant Professor of Radiation Oncology at Duke University Medical Center, Durham, NC. Since 2010, she has served as the director of the Breast Cancer Program in the Duke Cancer Institute, overseeing all basic and translational research programs involving breast cancer patients. Blackwell serves on the national Scientific Advisory Board of the Susan G. Komen Foundation. As one of the nation's leading breast cancer researchers, Blackwell has played a major role in developing therapies that represent revolutionary non-chemotherapy based approaches for treating breast cancer. Her work on promising new therapies that selectively target breast tumor cells led to her inclusion on TIME magazine's 2013 list of the 100 most influential people in the world. Blackwell has authored or co-authored more than 70 articles or book chapters. She has clinical and research interests in breast cancer angiogenesis, breast cancer in younger women, endocrine therapy, and targeted therapy for breast cancer and has served as the principal investigator or co-principal investigator of more than 50 clinical trials. Among her honors, Blackwell is a recipient of the Young Investigator Award in breast cancer from the Duke University Specialized Program of Research Excellence; the Duke Cancer Center Malek Family Award for outstanding cancer investigation; and the Joseph Greenfield Award for Mentorship of Clinical Research.

Dr. Adam M. Brufsky, MD, PhD, is Professor of Medicine at the University of Pittsburgh School of Medicine, Pittsburgh, PA. He serves as Co-Director, Comprehensive Breast Cancer Center and Medical Director, Women's Cancer Center at the Magee-Womens Hospital/UPCI, Pittsburgh, PA. He also serves as the Associate Division Chief for the Division of Hematology/Oncology within the University of Pittsburgh School of Medicine's Department of Medicine. Additionally, Dr. Brufsky is the Associate Director for Clinical Investigation for the University of Pittsburgh Cancer Institute. Dr. Brufsky is board certified in Internal Medicine and Medical Oncology by the American Board of Internal Medicine. He is an active member of the American Society of Clinical Oncology and the American Association for Cancer Research. He has numerous abstracts and research articles in leading journals, including the Journal of Clinical Investigation, Journal of Clinical Oncology, and Lancet. Dr. Brufsky is Principal Investigator on a number of research grants funded by the National Institutes of Health,

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Susan G. Komen Foundation, and US Army Breast Cancer Research Program.

Dr. Ana Maria Gonzalez-Angulo, MD, MSc, FACP, is Associate Professor, Department of Breast Medical Oncology and Chief, Section of Clinical Research and Drug Development, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center, Houston, TX. She is interested in aggressive types of breast cancer including triple receptor-negative disease. Her research focuses on mechanisms of resistance to standard breast cancer therapies, and on the development of markers to predict response to treatments using functional proteomics. She is funded by the NCI, ASCO, Komen for the Cure, AACR (SU2C) and the Commonwealth Foundation for Cancer research. She is the Chair of the Endocrine Resistance Working Group and a member of the Correlative Sciences Working Group for the Translational Breast Cancer Research Consortium, and a member of the Breast Cancer Committee of SWOG and of the BIG-NABG Triple Negative Working Group. Dr. Gonzalez-Angulo serves as a member of the steering committee of The United States – Middle East Partnership for Breast Cancer Awareness and Research and the Partnership for Breast Cancer Awareness and Research of the Americas.

Dr. Reshma Mahtani, DO is Assistant Professor of Clinical Medicine, Division of Hematology/Oncology, Miller School of Medicine, University of Miami, Miami, FL. Dr. Mahtani served as Sylvester Comprehensive Cancer Center's principal investigator on several Phase I, II and III breast and ovarian clinical trials. Her clinical interests include breast and gastrointestinal malignancies. She was the first author of numerous manuscripts related to breast, gastrointestinal and lung cancer.

Dr. Charles Vogel, MD is Professor of Clinical Medicine, Division of Hematology/Oncology, Miller School of Medicine, University of Miami, Miami, FL. His clinical and research interests involve all medical aspects of breast cancer treatment including anti-hormonal therapy, chemotherapy and "targeted therapy." During his 35 years of breast cancer research, he has participated in clinical trials of virtually every medical breast cancer treatment currently available. He was one of the clinical trial pioneers in Trastuzumab (Herceptin) therapy and more recently with Bevacizimab (Avastin) and Lapatanib (Tykerb). He was also one of the early pioneers in thedevelopment of clinical trials from within community practice. Currently the "Cancer Research Network" he founded has become the community clinical trials outreach program for the University of Miami. Dr. Vogel continues his interest in breast cancer clinical trials both through his involvement with the Breast Site Group of the Sylvester Comprehensive Cancer Center and through similar interactions with community oncologists within the Cancer Research Network.

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KOLs from Europe

Dr. Thomas Bachelot, MD, is Head of the Breast Cancer Unit and the Clinical Trial Unit at the Centre Leon Berard, Lyon, France. The Center handles up to 1,000 patients every year in clinical trials. Dr. Bachelot, who spent 2 years at Massachusetts Institute of Technology working in gene therapy, has been a breast cancer specialist since 1998 and has been an international clinical trial investigator for the past 10 years. He has also designed several clinical trials in metastatic breast cancer, among them the recently published TAMRAD (everolimus in addition to hormone therapy) and LANDSCAPE studies (lapatinib and capecitabine in patients with non-pretreated brain metastases from HER2-positive metastatic breast cancer).He is a member of the board of the Unicancer and GINECO cooperative groups and is currently working on early clinical development and the implementation of high-throughput technology for patient selection in biology-driven clinical trials.

Dr. Rob Coleman, MBBS, MD, FRCP, is Professor Department of Oncology, Weston Park Hospital, Sheffield, England, UK. He is an Associate Director of the National Cancer Research Network (NCRN) and the Lead for the new CR-UK / YCR Sheffield Cancer Centre. Dr. Coleman was Chairman of the National Cancer Research Institute Breast Cancer Study Group in the UK (2004-09) and Past-President of the Cancer and Bone Society (2005-08). He has developed a highly successful cancer clinical trials facility, which has both led and participated in a broad range of clinical trials. These have ranged from early-phase drug development studies to large Phase III randomised trials. As research lead for clinical cancer research, Coleman is responsible for running the Cancer Clinical Trials Centre, a purpose-built clinical research facility that provides the research infrastructure for the North Trent Cancer Research Network, the Experimental Cancer Medicine Centre, and the breast cancer component of the bone oncology research laboratories within the medical school. He is a frequent lecturer at national and international meetings on various aspects of breast cancer management, cancer induced bone disease and treatment related side effects. Dr. Coleman has worked with many societies, educational organisations and pharmaceutical companies organising educational meetings on both a national and international scale.

Dr. Alessandra Gennari, MD, PhD, is Medical Director, Medical Oncology Unit, Galliera Hospital, Genoa, Italy. She has authored 45 publications in medical journals on the treatment of breast cancer and is a reviewer for journals such as Lancet, Journal of Clinical Oncology, Annals of Oncology, and the British Journal of Oncology. Since 2004, Gennari has been a speaker at 70 national and international conferences on breast cancer and a principal investigator of several national and international breast cancer

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studies. She is a member of ASCO and ESMO, and the International Breast Cancer Study group.

Dr. Adrian L. Harris, MD, DPhil is Professor of Medical Oncology at the University of Oxford and Director of the Cancer Research UK Medical Oncology Unit. He is a Consulting Medical Oncologist at the National Health Service, Oxford Radcliffe Hospital Trust. Professor Harris's research is on tumour angiogenesis and hypoxia as key targets for anti-cancer therapy. He is the Director of the Molecular Oncology Laboratories, which comprises 11 research groups working in the areas of tumour hypoxia and angiogenesis, signal transduction and DNA repair.

Professor Gunter von Minckwitz is Managing Director of the German Breast Group (GBG) Research Institute. GBG is the largest cooperative group in Germany working in the field of breast cancer with approximately 530 centres, 1,100 collaborators and a recruitment of greater than 32,000 breast cancer patients into prospective clinical trials. He is also Alternate Director at Senologic Oncology, Breast Centre, Düsseldorf and a Professor and Consultant at the University Women's of Frankfurt, Germany. His areas of research include systemic treatment in all stages of the disease (neo-adjuvant, adjuvant, metastatic treatment and chemoprevention), where he has participated and led a large number of national and international clinical trials. He has improved the infrastructure for breast cancer trials all over Germany, and has founded and led the development of the national treatment guideline for breast cancer of the AGO from 2001 until 2006. Professor von Minckwitz has authored and co-authored more than 200 Medline listed scientific papers including, Journal of Clinical Oncology, Journal of the National Cancer Institute, Lancet, and the New England Journal of Medicine, in addition to 450 review articles, book chapters and printed abstracts, as well as 18 books. He is on the board of directors of the Breast International Group (BIG), and has become member of the St. Gallen consensus panel in 2008 and the Early Breast Cancer trialists' collaborative group (EBCTCG) in 2010. He received the Wertheim Award in 2009 and the Claudia-Schilling Award in 2012.

Dr. Rafael Trujillo is Medical Oncologist, Xanit International Hospital, Malaga, Spain. Dr. Trujillo practices within the Xanit Oncology Institute, which offers treatments in medical oncology, radiation oncology, linear accelerator, radioactive iodine, brachytherapy, psycho-oncology, genetic counseling, cancer diagnosis, positron emission tomography and computed axial (CAT scan), and scintigraphy. He has worked in a number of Spanish hospitals, including Carlos Haya University General Hospital of Malaga, Punta de Europa General Hospital of Algeciras, and Virgen de la Victoria University Hospital in Malaga. He is a practicing oncologist with over 12 years of

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experience, but also has experience working in the pharmaceutical industry (Celgene, Novartis , Bristol Myers Squibb) in the field of clinical protocol design. Dr. Trujillo has authored or co-authored over 100 publications in the field of breast cancer.

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