Introducing…

NCCN Academy for Excellence & Leadership in Oncology™

April 2009

Program Overview

In 2009, NCCN will launch the **NCCN Academy for Excellence & Leadership in Oncology™**, a series of oncology certificate programs tailored to meet the educational needs of cancer center administrators, clinical executive leaders, oncology fellows, and pharmaceutical/biotech professionals. The NCCN Academy for Excellence & Leadership in Oncology™ will bring together emerging leaders from each of these groups to learn from the top national experts in the business, administration, policy, and science of cancer.

The NCCN Academy for Excellence & Leadership in Oncology™ School of Pharmaceutical & Biotech Business seeks to educate pharmaceutical and biotechnology professionals about key scientific, policy, coverage, reimbursement and operational issues in oncology. Professionals from marketing, sales, medical affairs, clinical research, policy and governmental affairs, and other business areas all will benefit from their matriculation at the School of Pharmaceutical & Biotech Business. In the end, patients will benefit from an up-to-date, more-informed and focused cadre of business professionals in pharma/biotech companies.

Current marketplace conditions are calling for pharmaceutical professionals to gain more education in disease-specific contexts. The rapidly changing environment in the science, the clinical aspects, and the policy affecting the practice of oncology argues for ongoing education of key professionals in the pharma/biotech industry. Educational programs from the NCCN Academy for Excellence & Leadership in Oncology™ School of Pharmaceutical & Biotech Business can help pharmaceutical professionals integrate key advances and marketplace changes into their business operations and decisions. The need for education from an authoritative source is affirmed by the following:

- A recent Sermo Physician Survey indicating that physicians want highly trained and experienced, professional brand representatives with more robust initial training and intensive, ongoing professional development.

- The newly revised PhRMA Code on Interactions with Healthcare Professionals, which includes a provision asking companies to ensure that all their representatives are trained and have a sufficient knowledge of general science.

In the context of the two-day NCCN Academy for Excellence & Leadership in Oncology™ School of Pharmaceutical & Biotech Business program to be offered in April 2009, an expert faculty will present the following modules:

I. The World of Oncology: Terminology, Staging and Continuum of Care

This module emphasizes how these clinical points impact the selection and use of drugs and biologics in various care delivery settings, including:

- Concise overview of the clinical course of patients from the detection of a suspicious lesion, to diagnosis, through treatment, and into surveillance and follow up care.

- A discussion among expert clinicians regarding common terminology, important distinctions such as clinical versus pathological staging, principles of staging and the variety of treatment options (surgery, radiation, drugs and biologics).

- Cancer care delivery settings including academic cancer centers, community cancer centers, and community practices will be described, compared, and contrasted.

This session will also focus on the issue of the type and quanta of data needed to support the establishment of an indication for clinical use of an agent. The clinical interpretation of clinical trial (Phases I, II, and III) data in oncology will be discussed and contrasted with that in other areas of Medicine.

II. Structure and Key Decision-Makers in the U.S. Cancer Care Delivery System

This module describes the structure of and decision-making process for the delivery of care in the United States.

- The significance of national designations for oncology programs such as NCI and NCCN, and how administrative structures differ among academic centers, community centers, and private practices, leading to different paths for institutional decision-making.

- The role of oncologists, mid-level providers and other advanced practitioners in managing decisions about patient care will be discussed in the context of different care delivery settings, and the concept of multidisciplinary care in academic centers will be addressed.

- The intersection of clinical decision-making with financial issues will be discussed along with the roles and issues faced by billing managers and practice managers.

III. Public and Private Payors: Process, Policy and Practice in Coverage and Reimbursement

This module will review the use of coverage policy, reimbursement levels, preauthorization, patient co-pay, disease management, specialty pharmacy, and other payor trends with an eye to the types of data and information needed to achieve positive reviews and decisions from oncology payors.

- The structure, processes and programs used by payors to manage and control the use of drugs, devices, procedures and techniques will be described.
- Inherent differences and "pressure points" between public and private payors will be highlighted.
- Specific national payers and other stakeholder organizations, including United Healthcare, FDA, CMS, TEC, ECRI, Hays, AMCP, DOD and AHRQ will be discussed with respect to their impact and influence on payor policies and decisions.
- The role of both insured and self-insured employers in benefit design and coverage policy will also be discussed.

IV. The Organization and Structure of Cancer Policy in the United States: Roles, Programs, Influence, and Impact

This module addresses the programs and information products of patient (patient advocacy), provider (such as ASCO and NCCN) and other groups and their influence on decisions that impact access to and availability of drugs, devices and procedures to patients.

- Specifically, this section reviews and discusses the influence of the above groups in the legislative, regulatory, informational, and educational arenas.
- The interaction, or lack thereof, among governmental agencies such as the FDA, CMS, NCI, AHRQ, and others will be discussed.

- The decision-making processes for oncology policy in the United States will be briefly contrasted with European Union countries, Canada, Australia, and large emerging markets.

V. Use of and Impact of Information Products on Decision-Makers in Cancer Care

This module highlights specific case examples to illustrate the types and amounts of data needed to influence provider and payer organizations.

- Analysis of the value of specific clinical outcomes, the design, size and publication status of studies, and the influence and type of cost data used in decisions will be presented and discussed by leading experts in the field.
- Crucial issue of use of drugs and biologics beyond the FDA approved label with a particular emphasis on practice guidelines and drug compendia.
- Candid discussion on the "dos" and "don'ts" of interacting with organizations developing information products.
- Rules governing CME programs and non-CME programs will be presented.
- The emerging views and policies of academic cancer centers with respect to interacting with pharma/biotech companies and their representatives also will be discussed.
- The "dos" and "don'ts" of using NCCN, ASCO or other guidelines will be presented and discussed.

VI. Institutional Decision-Making: Pharmacy Budgeting, P & T, and Information Systems

This module focuses on academic and community cancer center approaches to pharmacy management in cancer care, including cancer treatment and supportive care options.

- Mock P & T (Pharmacy and Therapeutics Committee) meeting that presents the decision-making methods used by cancer centers and discusses the process and influence of P & T Committees.

- Selection of regimens, the process and influence of P & T Committees, internal guidelines/ pathways, standardized orders, pharmacy budget development, purchase agreements, disease management all will also be reviewed in the context of decision-making within oncology institutions.

VII. The Clinical Future: Orals, Targeted Therapies, BioMarkers, and More

This module will cover the impact of the advances in science on clinical practice, on payer programs, and patient decisions.

- Patient management issues associated with the increasing use of oral drugs, with the chronic administration of less toxic biologics, and the decision-driving impact of biomarkers will be discussed.

- The impact of these developments on the utilization and policy for of drugs and biologics will be emphasized.

VIII. The Cancer Care Delivery System: Buzz Words that Will and Won't Stick

This module explores hot topics in policy areas that will affect the use of drugs and biologics in the near future.

- Leaders throughout the oncology business sector will need to understand how the implementation (or the degree of implementation) of the following initiatives would be likely to impact practice and policy decisions about access to, availability of, and utilization of drugs and biologics:

    - Quality Measures, Quality Evaluation, Pay for Performance
    - Patient co-pays, Value-based Insurance, Oncology Formularies
    - Specialty Pharmacy, BioSimilars
    - Outcomes Research, Comparative Effectiveness, Cost, and Cost-Effectiveness

IX. Informatics and Information Systems and Drugs and Biologics

This module focuses on an area that must be understood in order to appreciate how centers and practices make decisions about clinical interventions.

- The integration of information into decision-assist tools designed to be used by clinicians or patients or by payers will be examined.

- The role of informatics tools such as EMR and CPOE in oncology will be discussed with a particular emphasis on how these tools may influence the use of drugs and biologics in clinical settings.