National Cancer Institute (NCI) National Cancer Advisory Board (NCAB) *ad hoc* Subcommittee on Experimental Therapeutics

Gaithersburg Marriott Washingtonian Center Gaithersburg, MD 3 September 2024 6:00 p.m.–7:00 p.m. EDT

SUMMARY

<u>Subcommittee Members</u> Dr. Richard J. Boxer, Chair Dr. Rose Aurigemma, Executive Secretary Dr. Nilofer S. Azad Dr. Anna D. Barker (absent) Dr. Andrea Hayes Dixon Dr. Howard J. Fingert (absent)

Other Participants Mr. Mark Alexander, NCI Dr. Callisia N. Clarke, NCAB^{*} Dr. Gary L. Ellison, NCI Ms. Tamika Felder, NCAB^{*} Dr. Samantha Finstad, NCI Ms. Anne Lubenow, NCI Ms. Julie Papanek Grant Dr. Amy B. Heimberger (absent) Dr. Nikan Khatibi (absent) Dr. Susan Thomas Vadaparampil Dr. Ashani T. Weeraratna

Dr. Diane Palmieri, NCIDr. Bhadrasain Vikram, NCIDr. Karen M. Winkfield, NCABMs. Joy Wiszneauckas, NCIDr. Amanda Cenname, The Scientific Consulting Group, Inc., Rapporteur

Welcome and Opening Remarks

Dr. Richard J. Boxer, Clinical Professor, David Geffen School of Medicine, University of California, Los Angeles

Dr. Richard J. Boxer, Subcommittee Chair, welcomed the participants to the NCAB *ad hoc* Subcommittee on Experimental Therapeutics (Subcommittee) meeting. He remarked that the Subcommittee members have been considering how to foster collaborations among advocacy groups, academia, private industry, NCI, and the U.S. Food and Drug Administration. They previously suggested organizing a large workshop to bring together these groups, with a common goal of improving patient care through basic science, translational science, and advocacy.

The Subcommittee also is interested in fostering engagement between NCI and venture capitalists to advance novel discoveries in this area. Dr. Boxer expressed appreciation to Ms. Julie Papanek Grant for sharing her expertise in this area. He noted that Ms. Papanek Grant has provided insight into the lack of communication between small companies and NCI. Dr. Boxer is interested in fostering discussions between venture capitalists and NCI leadership to help address communication gaps. He added that

^{*} Pending appointment.

Dr. W. Kimryn Rathmell, Director, NCI, has expressed strong support for this concept. These efforts could serve as a pilot for other future NCI initiatives.

Dr. Rose Aurigemma, Executive Secretary, commented that the Subcommittee is interested in driving new therapies into the public domain; industry investments can enable opportunities in this area. NCI is interested in better understanding the interests of investors and encouraging them to provide more support in this space, particularly for later-stage research.

Briefing on Development of Workshop Ideas and Outreach to Venture Capital

Dr. Boxer and Ms. Julie Papanek Grant, General Partner, Canaan

Ms. Papanek Grant spoke on ideas for fostering discussions and outreach on this topic. She indicated that NCI has deep expertise and resources that can accelerate bringing new experimental treatments to patients but that more work is needed to communicate about opportunities for engagement with the federal government. Most private industry partners interact with NCI through its Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs.

Ms. Papanek Grant noted that many successful outcomes, such as work performed through the RAS Initiative, reflect successful partnerships between NCI and private industry entities. She underscored the importance of discourse connectivity, productive dialogue, and relationship building. She also pointed out that government and industry are focused on different priorities, which should be considered in this context. Navigating conflicts of interest will be critical.

Discussion

In response to a question from Dr. Karen M. Winkfield, Ms. Anne Lubenow provided additional details on the RAS Initiative. She explained that the program functions as a hub-and-spoke model, with the Frederick National Laboratory for Cancer Research (FNLCR) as the central hub and academic centers and industry partners as the surrounding spokes. The current discussion, however, is focused on providing an avenue for private industry entities to engage with NCI. Dr. Nilofer S. Azad noted that NCI's size and bureaucracy can impede efficient engagement.

Dr. Andrea Hayes Dixon suggested that the new NIH and NCI directors consider new approaches for fostering engagement with both private industry partners and academic investigators (e.g., through quarterly open seminars). Dr. Ashani T. Weeraratna remarked that differences in research priorities should be addressed; venture capitalists are generally most interested in funding cutting-edge scientific breakthroughs. Current perceptions about NCI's research priorities should be addressed in this context, and messaging to the scientific community will be critical.

Overview of NCI Support Mechanisms to Advance Drug Candidates

Dr. Rose Aurigemma, Associate Director, Developmental Therapeutics Program, Division of Cancer Treatment and Diagnosis (DCTD), NCI

Dr. Aurigemma outlined NCI's support mechanisms for advancing new therapeutics into the commercial sector, with a focus on bringing more drugs to patients and recruiting partners and investors. NCI's Division of Cancer Treatment and Diagnosis currently supports the extramural community through research project grants, resource programs (e.g., NCI Experimental Therapeutics [NExT], Stepping Stones), and SBIR/STTR programs. NCI's Center for Cancer Research supports the intramural community through the NCI Technology Transfer Center, Invention Development Program, and Drug Development Collaborative.

Dr. Aurigemma remarked that existing partnerships have been necessary for bridging gaps between intramural research and private industry; typically, this work is too early in development to attract interest from industry. In general, more avenues are needed for communicating outcomes of NCI-funded research. She noted that NCI's SBIR/STTR programs convene meetings to match investigators with potential venture capitalists. Ms. Lubenow added that NCI has worked to highlight technologies developed by intramural investigators, with a focus on potential commercialization, through its Startup Challenges program.

Discussion

Ms. Papanek Grant commented that a complex ecosystem of funding priorities is present within private industry; understanding the nuances within this ecosystem is critical. Dr. Azad inquired about specific gaps that currently are present among small biotechnology companies. Ms. Papanek Grant explained that funders are interested in new drugs that offer high potential for capitalization. Enrollment at cancer sites also remains an ongoing challenge. Dr. Azad highlighted the need for partnerships that bridge enrollment gaps by leveraging NCI resources, leading to expanded capabilities and cost savings.

Dr. Aurigemma noted that DCTD's Cancer Therapy Evaluation Program previously funded R21 grants for clinical trials, but this system had several limitations resulting from product delays and funding expirations. She added that NCI is interested in de-risking products and attracting the interest of private companies for those products; an external advisory committee can provide insights in this area. She also noted that NCI could provide investigators with development plans that could inform their data collection efforts.

Dr. Susan Thomas Vadaparampil underscored the importance of encouraging investigators to think beyond publication of their findings, with a focus on next steps for development. She noted that supplement awards can help enable progress in this area (e.g., through community partnerships). In response to a question from Dr. Aurigemma, Dr. Weeraratna explained that the SBIR/STTR program applicants have already established such partnerships. Ms. Papanek Grant added that the scale of capital also plays a role in these dynamics. She remarked that the SBIR/STTR programs fill a critical gap in this space.

Discussion of Workshops and Outreach

Dr. Boxer, Ms. Papanek Grant, and Subcommittee Members

Ms. Papanek Grant remarked that mechanisms are needed to foster partnerships through interactions rather than targeted matching efforts. Culture and strategy play important roles in this space. Dr. Winkfield added that a variety of investors exists, and hubs could help foster entrepreneurship and collaboration across the country. Ms. Papanek Grant pointed to Dr. Frank McCormick's work within the RAS Initiative as a successful example of academic and industry collaboration. A close understanding of industry operations and priorities is critical to such efforts.

Dr. Hayes Dixon highlighted the need for structured and tangible systems for fostering partnerships. Ms. Lubenow pointed out that several former NCI directors now work as venture capitalists and that their perspectives would be valuable for this discussion. Ms. Papanek Grant suggested considering the ultimate goal of these efforts (e.g., openings, roles, offices, dialogues). More work will be needed to formulate these goals, and communication among groups will be essential. Dr. Hayes Dixon commented that these activities are centered on the common goal of eliminating cancer. NCI's mission and vision must be at the forefront of such efforts, and open discussions will be essential for success in this space.

In response to a question from Dr. Azad, Ms. Papanek Grant explained that the Subcommittee's feedback will help inform the purpose and direction of the workshop. She commented on the importance of

considering the interests of industry partners, with a focus on the most promising potential medicines, innovations, and technologies. Dr. Aurigemma added that an NCI technology development office could help serve the needs of the extramural community; resources in this area could be particularly beneficial for trainees.

Dr. Boxer summarized the Subcommittee's discussions, noting that the participants highlighted the importance of fostering communication, breaking down silos, aligning with incentives, and bringing together partners with a common goal of ending cancer. The Subcommittee members agreed to reconvene in December 2024 and to develop a structured plan in advance.

Dr. Vadaparampil suggested developing a problem statement to focus these efforts. Dr. Aurigemma noted that a roundtable discussion among venture capitalists, organized by focus areas, could be beneficial. Dr. Boxer suggested including former NIH and NCI directors in the discussions. Ms. Papanek Grant proposed considering both the national and institutional infrastructure. Dr. Aurigemma highlighted the importance of continuing to support under-resourced institutions.

The Subcommittee members concluded by speaking on the importance of fostering collaborations to accelerate development within an inherently competitive space. Ms. Lubenow pointed out that the FNLCR was originally established to create a space where NCI investigators could work in parallel with private industry entities. Ms. Papanek Grant spoke on the complexities of work within this space; timing plays a key role in success, and ongoing conversations will be critical.

Adjournment

In response to discussion among several Subcommittee members, Ms. Lubenow remarked that Dr. Rathmell is currently formalizing an orientation across NCI's advisory committees. Dr. Boxer thanked the participants for their engagement and adjourned the meeting at 7:13 p.m. EDT.

Dr. Richard J. Boxer Chair Date

Dr. Rose Aurigemma Executive Secretary Date